

गोपनीय : Confidential

मिसिल स.- 8(5)/2013 डी.पी./एन पी पी ए- डीवी-II

F. No. 8(5)/2013/DP/NPPA-Div. II

कार्यवाही स. : 137/5/2013/F

Proceeding No : 137/5/2013/F

Minutes of the 137<sup>th</sup> and 5<sup>th</sup> meeting of Authority under DPCO  
2013 held on 22<sup>nd</sup> July, 2013 at 12.30 P.M.,

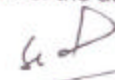
The 137<sup>th</sup> and 5<sup>th</sup> meeting of Authority under DPCO 2013 was held on 22<sup>nd</sup> July, 2013 at 12.30 P.M. under the chairmanship of Shri C. P. Singh Chairman, NPPA. The following members of the NPPA were present:-

- (i) Shri Sanjay Kumar, Member Secretary, NPPA.
- (ii) Shri K.L Prasad, Member (Ex-Officio), Adviser, Economic Division, Dept. of Economic Affairs.
- (iii) Shri Chandra Sekhar, 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 R. Asokan, Director (Pricing)
- (ii) Shri A.K. Saha, Director (Overcharging)
- (iii) Shri Jagdish Kumar, Director (M&S)
- (iii) Shri S. K. Bhatt, Dy. Director (Technical)
- (v) Smt Manmohan Kaur, Dy. Director (Cost)
- (vi) Shri Manish Goswami, Dy. Director (Cost)
- (vii) Shri S.S. Agarwal, Asstt. Director (Cost)

Leave of absence was granted to Ms. Aruna Sethi Advisor (Cost) & ex-officio member of the authority.

  
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**Agenda Item no. 1**

1. Members of the Authority who participated in the 136<sup>th</sup> and 4<sup>th</sup> Meeting under DPCO, 2013 confirmed the minutes of the meeting.
2. **Action Taken Report:** Noted

The Authority was informed that as per the decision taken in the last meeting held on 05.07.2013, price fixation orders have been issued in respect of 25 cases of scheduled formulations under DPCO 2013.

**Agenda Item no. 3:**

3. The Authority had detailed deliberations regarding the price fixation of scheduled formulations under DPCO, 2013 relating to 26 fresh cases proposed in the Agenda. The Authority also recalled the deliberations held during the 1<sup>st</sup> meeting and noted that the data of IMS Health is not complete and accurate and that IMS may have done extrapolation of the figures in some cases. Therefore, NPPA has certain limitations in this regard. The data available on the internet is also not complete and may not be considered as the PTR. Moreover the market share is not indicated in this data. Therefore, NPPA has taken a view that initially the prices may be worked out based on the IMS Health data and later on revisited in extra-ordinary circumstances and in public interest at large, if called for. Therefore, the Authority considered each case and approved the prices of all the 26 formulation packs for fixing / notifying the ceiling price under para 4 of DPCO, 2013. A Statement showing the prices approved and percentage of decrease from the highest price in the zone of consideration in respect of each medicine is enclosed as Annexure A as mentioned above.

  
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**Agenda Item no. 4:**

4. Authority was informed that representation from I.V. Fluid manufacturers / associations has been received by NPPA wherein it is stated that the price of a Non-scheduled product namely glucose injection with 5% was fixed under para 10(b) of DPCO, 1995 and was revised in the year 2011 based on 'cost plus method' under the provisions of DPCO, 1995 and notified prices were the ceiling prices to be followed by all manufacturers. It also noted that at the same time under the DPCO, 2013 the prices have been fixed vide notification no. 1818(E) dated 21.06.2013. It was further noted that since price of the product was fixed under para 10(b) of DPCO, 1995, the present price fixation of these medicines under DPCO, 2013 is creating confusion and a large number of representations have been received from companies and industry associations seeking clarification in this regard. The Authority also noted that the Department of Pharmaceuticals in consultation with the Department of Legal Affairs has conveyed that once the price of a Non-scheduled item is fixed by NPPA, the formulation loses its character of 'Non-Scheduled' item and becomes a 'deemed to be Scheduled formulation'. In view of the above, the Authority decided to withdraw the price notified vide notification S.O. 1818(E) dated 21.06.2013 and also decided that the prices fixed in 2011 vide S.O. 2710(E) dated 28.11.2011 may be continued subject to the provisions under para 10 of DPCO, 2013.

**Agenda Item no. 5:**

5. It was informed to the Authority that the price of 'Oral Rehydration Salt (ORS)' was fixed as per section 26.1 of DPCO, 2013 and the price was fixed as Rs. 0.58/g vide notification S.O. 1696(E) dated 14.06.2013 as per the data provided by IMS-Health. M/s. FDC has submitted their submissions regarding the price of ORS which is also appearing under Section 17.6.1 of the Schedule - I of the DPCO for ORS as per IP. It was also informed to the Authority that as per the data provided by IMS-Health, the price in respect of ORS under Section 17.6.1 of the DPCO, 2013 works out to Rs. 0.61/g. The

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Authority discussed and noted that IMS has informed that the exact composition for each ORS was not readily available with IMS Health to segregate it further which is confirming to the composition given in the Schedule - I as per the I.P. and hence the incorrect data was furnished by them. The Authority noted that the price of ORS needs to be fixed only after re-checking of the data provided by IMS-Health under Section 17.6.1. Since the prices to be notified for ORS will be made applicable for formulation under both the sections i.e. 17.6.1 and 26.1 of Schedule I of DPCO, 2013, it may not be appropriate to continue with the price earlier notified for section 26.1 vide notification S.O. 1696(E) dated 14.06.2013. Therefore, the Authority decided to withdraw the notification S.O. 1696(E) dated 14.06.2013 and directed NPPA to get revised data from IMS-Health and analyse the same for price fixation of ORS under DPCO 2013 and put up to the Authority for decision.

**Agenda Item no. 6:**

6. The Authority discussed the Review Order passed by the Department of Pharmaceuticals (DOP) against the price fixation order S.O. 1513(E) dated 01.07.2011 under DPCO, 1995 in respect of price fixation of Pyrantel Pamoate Suspension 10 ml bottle of M/s. IPCA. As per the advice of the DOP, after announcement of DPCO, 2013, the cases pending for disposal under DPCO, 1995 are to be finalized. Accordingly, the proposal is approved by the Authority revising the ceiling price of Rs. 10.92 to Rs. 11.68 per pack.

**Agenda Item no. 7:**

7. The Authority discussed the Review Order passed by the Department of Pharmaceuticals (DOP) against the price fixation order S.O. 3017(E) dated 27.12.2012 under DPCO, 1995 in respect of price fixation of Nor-Metrogyl Suspension 30ml bottle with measuring cup of M/s. Lekar Pharma. As per the advice of the DOP, after announcement of DPCO, 2013, the cases pending for disposal under DPCO, 1995 are

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to be finalized. Accordingly, the proposal is approved by the Authority revising the ceiling price of Rs. 11.20 to Rs. 11.56 per pack.

8. The Chairman, NPPA emphasised the need for putting up separate notes under specific agenda items in every meeting regarding the availability of NLEM drugs, Status of Overcharging cases and Monitoring and Enforcement of prices as per the provisions of DPCO, 2013.

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

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(Sanjay Kumar)  
Member Secretary

NATIONAL LIST OF ESSENTIAL MEDICINES 2011						Annexure-A		
Section: 1 – Anesthesia								
1.1 General Anesthetics and Oxygen								
Sl. No.	Medicines	Category	Route of Administration	Strengths	MRP excl. local taxes (Rs./unit)	Maximum	Minimum	% reduction wrt max.
1	Isflurane	S, T	Inhalation		10.73/ml	11.47	7.52	19.32
Section: 2 - Analgesics , Antipyretics, Nonsteroidal Anti-inflammatory Medicines, Medicines used to treat Gout and Disease Modifying Agents used in Rheumatoid Disorders								
2.1: Non-Oploid Analgesics, Antipyretics and Nonsteroidal Anti-inflammatory Medicines								
Added medicines								
2	Tramadol	S, T	Injection	50 mg/ml	11.73/ml	17.49	1.75	42.16
Section: 3 – Antiallergics and Medicines used in Anaphylaxis								
3	Chlorpheniramine Maleate	P, S, T	Tablets	4 mg	0.10	0.37	0.03	76.21
4	Hydrocortisone Sodium Succinate	P, S, T	Injection	100 mg	37.13	67.90	15.05	44.72
Section: 4 - Antidotes and Other Substances used in Poisonings								
4.2: Specific								
5	Naloxone	P, S, T	Injection	0.4mg/ml	91.51	108.16	64.00	27.06
Section: 6 – Anti-infective Medicines								
6.2 Antibacterials								
6.2.1 Beta lactam medicines								
6	Ceftriaxone	S, T	Injection	1 g	55.44	76.42	19.50	37.46
Added Medicines								
7	Cefixime	T	Tablet	200mg	11.25	24.04	4.66	59.65
6.2.2 Other antibacterials								
	Medicines	Category	Route of Administration/ Dosage Form	Strengths				
8	Azithromycin	S, T	Suspension	100mg/5ml	1.55/ml	2.73	0.51	50.83
6.2.4 Antituberculosis medicines								
	Medicines	Category	Route of Administration/ Dosage Form	Strengths				
9	Isoniazid	P, S, T	Tablets	300 mg	1.27	1.22	0.98	9.70
10	Ofloxacin	S, T	Tablets	200 mg	4.90	26.69	1.14	84.16
Section: 7 –Antimigraine medicines								
7.2: For Prophylaxis								
11	Propranolol hydrochloride	P, S, T	Tablets	10 mg	1.09	1.00	0.85	6.33
Section: 8 – Antineoplastic, immunosuppressives and medicines used in palliative care								
8.2: Cytotoxic medicines								
12	Cisplatin	T	Injection	10 mg / vial	84.84	113.68	58.95	35.67
13	Methotrexate	T	Injection	50 mg / ml	33.18/ml	39.27	23.53	27.15
Added medicines								
14	Mesna	T	Injection	200 mg	24.57/ml	39.96	11.26	46.99
8.4: Medicines used in palliative care								
15	Ondansetron	S, T	Tablets	4 mg	4.76	7.50	0.50	45.26
Section: 10 –Medicines affecting the blood								
10.1: Antianaemia medicines								
16	Iron Dextran	S, T	Injection	50 mg (iron/ml)	28.71/ml	58.17	6.58	57.46
10.2: Medicines affecting coagulation								
Added Medicines								
17	Enoxaparin	T	Injection	40mg	439.39	655.27	280.78	42.19
Section: 12 –Cardiovascular medicines								
12.1: Antianginal medicines								
18	Metoprolol	P, S, T	Injection	1mg/ml	2.01/ml	2.48	1.79	9.36
12.2: Antiarrhythmic medicines								

NATIONAL LIST OF ESSENTIAL MEDICINES 2011						Annexure-A		
19	Lignocaine Hydrochloride	S, T	Injection	2%	1.00/ml	1.70	0.53	49.41
Section: 15 – Disinfectants and antiseptics								
15.1: Antiseptics								
20	Cetrimide	P, S, T	Solution	20% (conc. for dilution)	0.43/ml	0.41	0.34	8.65
Section: 16 – Diuretics								
21	Mannitol	P, S, T	Injection	10%	0.69/ml	1.00	0.19	40.34
Section: 19 Immunologicals								
19.2: Sera and immunoglobins								
22	Polyvalent Antisnake Venom	P, S, T	Injection	10 ml	410.56	411.60	302.50	14.01
Section: 21 – Ophthalmological Preparations								
21.4: Miotics and Antiglaucoma medicines								
23	Timolol Maleate	P, S, T	Drops	0.25%	4.46/ml	5.08	3.12	24.28
24	Timolol Maleate			0.50%	12.07/ml	22.80	6.12	54.36
22.1: Oxytocics								
25	Mifepristone	T	Tablets	200mg	357.13	446.90	249.70	31.11
Section: 27 – Vitamins and Minerals								
26	Calcium carbonate	P, S, T	Tablets	500 mg	1.67	1.90	0.37	24.33