

गोपनीय: Confidential

मिसिलस.- 8(38)/2016/डी.पी./एनपीपीए- डीवी-II

F. No. 8(38)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 170/38/2016/F

Proceeding No : 170/38/2016/F

Minutes of the 170th and 38th meeting of Authority under DPCO, 2013 held on 09.11.2016 at 11.00 AM.

- I. 1. The 170th overall meeting of the Authority, which is the 38th under the DPCO, 2013 was held on 09th November, 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) Dr. G.N. Singh, DCG(I).
- (iii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iv) Shri R.Chandrashekhar, Deputy Drug Controller, Deptt. of Health & Family Welfare.

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

- (i) Shri Katyan Nag, Adviser (Cost)
- (ii) Shri A.K. Khurana, Director (Pricing/Admn.)
- (v) Shri A.P.S. Sawhney, Director (Overcharging/M&E)
- (vi) Shri Rakesh Kakkar, Deputy Director (M&E)
- (vii) Shri Baljit Singh, Asstt. Director (Pricing)
- (viii) Shri Prasenjit Das, Asstt. Director (Pricing)
- (ix) 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 37th Meeting held on 06.10.2016.

The Authority confirmed the minutes of the of overall 169th and the 37th Meeting under DPCO, 2013 to the following:-

2. Agenda Item no. 2: Action Taken Report

2.1 Noted.

2.2 Further, in case of Paracetamol 80mg suppository, Paracetamol 160mg suppository, Paracetamol 125mg/5ml Oral Liquid and Paracetamol 120mg/5ml Oral Liquid, keeping in view the high incidence of dengue and chikungunya fever, the Authority decided in the previous 37th meeting to put on hold the approved price notifications till the crisis situation eased, so that availability of Paracetamol based formulations would not be adversely affected. The Authority after discussions in the meeting observed that newspaper reports about dengue and chikungunya were less now. Further, one of the companies manufacturing the said formulations

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(M/s GSK Ltd. vide letter dated 19.9.2016) informed NPPA/Govt. that paracetamol formulations are effective in management of dengue and chikungunya. The company also assured the Government & its department to ensure availability of the formulations to all patients.

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 discussed in detail the data and calculation sheets of 39 formulations at the meeting. The Authority approved the ceiling prices in respect of all the following 39 formulations.

S. NO.	Unique No. as per NLEM	Name of the formulation/ composition	Strength	Dosage Form	Unit for Ceiling Price	Approved ceiling price under NLEM, 2015 (Rs.)
I A. COMMON CASES						
Section 3-Antiallergics and medicines used in anaphylaxis						
1	3.6	Pheniramine	22.75 mg/ml	Injection	Per ML	1.03
Section 4-Antidotes and other substances used in poisoning						
2	4.2.7	Naloxone	0.4 mg/ml	Injection	Per ML	80.49
Section 5-Anticonvulsants/ Antiepileptics						
3	5.5	Lorazepam	2 mg/ml	Injection	Per ML	7.22
4	5.6	Phenytoin	25 mg/ml	Injection	Per ml	2.33
Section 6-Anti infective medicines						
6.2-Antibacterials						
6.2.1-Beta lactam medicines						
5	6.2.1.10	Ceftazidime	250 mg	Powder for Injection	Each Pack	60.39
6	6.2.1.10	Ceftazidime	1 gm	Powder for Injection	Each Pack	194.19
6.5-Antiprotozoal Medicines						
6.5.3.1-For curative treatment						
7	6.5.3.1.3	Artesunate (A) + (Sulphadoxine + Pyrimethamine) (B)	1 Tablet 50 mg (A) + 1 Tablet (500 mg + 25 mg) (B)	Combi Pack	Per Combi Pack	19.69
Section 8 -Antineoplastic/ immunosuppressives and medicines used in palliative care						
8.4-Medicines used in palliative care						
8	8.4.10	Metoclopramide	5 mg/ml	Oral Liquid	Per ml	0.41
Section 12-Cardiovascular medicines						
12.5-Antithrombotic medicine (Cardiovascular/Cerebrovascular)						
9	12.5.4	Streptokinase	7,50,000 IU	Injection	Each Pack	1,168.12
10	12.5.4	Streptokinase	15,00,000 IU	Injection	Each Pack	1,660.84
Section 14-Dermatological medicines (Topical)						
14.2-Anti-infective medicines						

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11	14.2.4	Povidone iodine	5%	Solution	Per ML	0.33
14.3--Antiinflammatory and antipruritic medicines						
12	14.3.1	Betamethasone	0.05%	Cream	Per GM	0.54
Section 15 -Diagnostic agents						
15.1-Ophthalmic medicines						
13	15.1.3	Tropicamide	1%	Eye drop	Per ML	9.34
Section 17-Disinfectants and antiseptics						
17.1-Antiseptics						
14	17.1.1	Cetrimide	20% (concentrate for dilution)	Solution	Per ML	0.29
Section 18-Diuretics						
15	18.3	Mannitol	20%	Injection	Per ML	0.27
Section 20-Gastrointestinal medicines						
20.1-Antiulcer medicines						
16	20.1.3	Ranitidine	25 mg/ml	Injection	Per ML	1.48
20.4-Antispasmodic medicines						
17	20.4.1	Dicyclomine	10 mg/ml	Injection	Per ML	2.44
Section 25-Ophthalmological Medicines						
25.1-Anti-infective medicine						
18	25.1.2	Ciprofloxacin	0.30%	Ointment	Per GM	1.04
19	25.1.4	Gentamicin	0.30%	Drops	Per ML	0.84
25.4-Miotics and antiglaucoma medicines						
20	25.4.2	Pilocarpine	2%	Drops	Per ML	9.38
21	25.4.3	Timolol	0.25%	Drops	Per ML	4.79
25.5-Mydriatics						
22	25.5.1	Atropine	1%	Drops	Per ML	3.05
23	25.5.2	Homatropine	2%	Drops	Per ML	5.53
Section 26-Oxytocics and Antioxytocics						
26.2-Medicines used in pre term labour						
24	26.2.1	Betamethasone	4 mg/ml	Injection	Per ML	3.89
Section 28-Medicines acting on the respiratory tract						
28.1-Antiasthmatic medicines						
25	28.1.3	Hydrocortisone	200 mg	Injection	Each Pack	53.39
Section 4-Antidotes and other substances used in poisoning						
26	4.2.10	Pralidoxime chloride (2-PAM)	25 mg/ml	Injection	Per ML	3.45
B. NEW CASES						
Section 6-Anti infective medicines						
6.4-Antiviral medicines						
6.4.3.2-Non-nucleoside reverse transcriptase inhibitors						
1	6.4.3.2.1	Efavirenz	200 mg	Tablet	Per Tablet	20.17
ii C. COMMON (Explanation to Schedule-I)						
Section 6-Anti infective medicines						
6.2-Antibacterials						

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6.2.3-Antileprosy medicines						
6.2.4-Antituberculosis medicines						
1	6.2.3.3 6.2.4.13	Rifampicin	300 mg	Tablet	Per Tablet	2.72
6.3-Antifungal medicines						
2	6.3.3	Fluconazole	100 mg	Capsule	Per Capsule	23.44
3	6.3.3	Fluconazole	200 mg	Capsule	Per Capsule	33.87
6.4-Antiviral medicines						
6.4.3-Antiretroviral medicines (Anti HIV)						
6.4.3.2-Non-nucleoside reverse transcriptase inhibitors						
4	6.4.3.2.1	Efavirenz	200 mg	Capsule	Per Capsule	21.43
5	6.4.3.2.1	Efavirenz	600 mg	Capsule	Per Capsule	55.81
6.4.3.4-Protease inhibitors						
6	6.4.3.4.4	Ritonavir	100 mg	Capsule	Per Capsule	26.18
D. NEW (Explanation to Schedule-I)						
Section 8 -Antineoplastic/immunosuppressives and medicines used in palliative care						
8.1-Antineoplastic medicines						
1	8.1.23	Imatinib	400 mg	Capsule	Per Capsule	236.99
Section 10-Medicines affecting blood						
10.1-Antianaemia medicines						
2	10.1.4	Folic acid	5 mg	Capsule	Per Capsule	5.23
Section 14-Dermatological medicines (Topical)						
14.4-Medicines affecting skin differentiation and proliferation						
3	14.4.1	Benzoyl peroxide	2.50%	Cream	Per GM	2.18
Section 21-Hormones, other endocrine medicines and contraceptives						
21.5-Ovulation Inducers						
4	21.5.1	Ciomiphene	100 mg	Capsule	Per Capsule	51.64
Section 25-Ophthalmological Medicines						
25.4-Miotics and antiglaucoma medicines						
5	25.4.1	Acetazolamide	250 mg	Capsule	Per Capsule	4.03
Section 28-Medicines acting on the respiratory tract						
28.1-Antiasthmatic medicines						
6	28.1.5	Salbutamol	4 mg	Capsule	Per Capsule	0.56

4. Agenda item no. 4: Fixation of retail price in respect of new drugs.

4.1 The Authority discussed the following 11 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 Retail Price (Rs.)
4(i)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s Macleods Pharmaceuticals Ltd. (Marketing company) - Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 1000mg (SR) - (Tenlimac M 1000)	Rs. 11.65/tablet

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	tablet).	
4(ii)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s Torrent Pharmaceuticals Ltd. (Marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 1000mg (SR) – (Tenzulix M 1000 tablet).	Rs. 11.65/tablet
4(iii)	M/s Cadila Healthcare Ltd. (Manufacturer as well as Marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 1000mg (SR) – (Tenglyn M 1000 tablet).	Rs. 11.65/tablet
4(iv)	M/s Lupin Ltd. (Manufacturer as well as Marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 1000mg (SR) – (Teneligliptin 20mg and Metformin HCl (SR) 1000mg tablet).	Rs. 11.65/tablet
4(v)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s Torrent Pharmaceuticals Ltd. (Marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 500mg (SR) – (Tenzulix M 500 tablet).	Rs. 11.14/tablet
4(vi)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s Macleods Pharmaceuticals Ltd (Marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 500mg (SR) – (Tenlimac M 500 tablet).	Rs. 11.14/tablet
4(vii)	M/s Glenmark Pharmaceuticals Ltd. (Manufacturer) and M/s M/s Anthem BioPharma Pvt. Ltd. (Marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 500mg (ER) – (Teneligliptin 20mg and Metformin HCl (ER) 500mg tablet).	Rs. 11.14/tablet
4(viii)	M/s Windlas Biotech Ltd. (Manufacturer as well as Marketing company) – Diclofenac Sodium 50mg and Paracetamol 325mg tablet – (Diclofenac Sodium & Paracetamol tablet).	Rs. 2.30/tablet
4(ix)	M/s Cadila Healthcare Ltd. (Manufacturer as well as Marketing company) - r-HuErythropoietin (r-HuEPO) 40000 IU – (Zyrop 40000 Injection).	Rs. 8938.96/ Each Pack
4(x)	M/s Cadila Healthcare Ltd. (Manufacturer as well as Marketing company) - r-HuErythropoietin (r-HuEPO) 20000 IU – (Zyrop 20000 Injection).	Rs. 4925.59/ Each pack
4(xi)	M/s Synkem Pharmaceuticals Ltd. (Manufacturer) and M/s Ajanta Pharma Ltd. (Marketing company)– Metformin HCl (in sustained release form) – 500mg and Voglibose 0.3mg – (Voglibose + Metformin SR tablet).	Rs. 57.62/10 tablets

5. **Agenda Item no. 5: Representation for Price revision of Carboxymethylcellulose Drops 1% and 0.5% notified vide S.O. 1561(E) dated 27.4.2016.**

5.1 (A) This case was discussed in detail and the Authority approved the revised ceiling price of Carboxymethylcellulose Drops 1% at Rs. 16.44 per ml.

(B) This case was discussed in detail and the Authority approved the revised ceiling price of Carboxymethylcellulose Drops 0.5% at Rs. 11.85 per ml.

6. **Agenda Item no. 6: Discontinuation of Dinmek 30's tablet (Tenofovir 300mg+ Lamivudine 300mg + Efavirenz 600mg) under para 21(2) of DPCO, 2013 by M/s MSD Pharmaceuticals Pvt. Ltd.**

6.1 The matter was discussed. It was deferred to collect information whether formulation is covered under National AIDS control programme or any other government programme.

7. **Agenda Item no. 8: Discontinuation of Viraferonpeg 100mcg Injection (Pegylated interferon alfa 2b) under para 21(2) of DPCO, 2013 by M/s Fullford (I) Ltd.**

7.1 The matter was discussed. It was deferred to check about the impact of discontinuation of the product, as it is used in the treatment of hepatitis B and C.

8. **Agenda Item No. 9: Discontinuation of Clindatime 150 Capsule (Clindamycin) under para 21(2) of DPCO, 2013 by M/s Mankind Pvt. Ltd.**

8.1 The matter was not discussed. Deferred for ^{the} next Authority Meeting.

Additional agenda items circulated during the meeting:-

9. **Agenda Item no. 6: Status of Review orders issued by DOP which are pending with NPPA for implementation.**

9.1 Noted.

10. **Status of Court cases**

10.1 The Authority put on record its deep appreciation of the efforts of Sh. Suneel Chopra, Principal Legal Consultant (PLC) and his team in pursuing Civil Appeal 329/2005 filed by UOI vs. M/s Cipla Ltd. and connected cases in which the Hon'ble Supreme Court on 21.10.2016 pronounced its landmark judgment in favour of the Government/NPPA. These cases were extremely important, having great magnitude and involved issues relating to validity of norms and price notifications, high financial implications involving Rs. 3,500 crores (approx) and public interest. The Judgment upheld price notifications issued under DPCO 1995 which will help the Government/NPPA to recover its long pending overcharging dues from the concerned companies.

10.2 The Hon'ble Supreme Court of India on 20.7.2016 remanded/disposed of 15 transfer cases and 5 Writ Petitions with the direction to the concerned companies to deposit overcharged amounts with the Govt./NPPA. Accordingly, an amount of more than Rs. 220 crores (approx) has been recovered so far during the last two months. The Authority complimented the relentless efforts by Sh. Suneel Chopra, Principal Legal Consultant (PLC) and his team in pursuing these cases too.

10.3 The Authority also noted that Price notifications issued by NPPA on 10.7.2014 in respect of 108 formulations (anti-diabetic and cardiovascular) under paragraph 19 of DPCO, 2013 have

been upheld by the Hon'ble High Court of Bombay vide order dated 26.9.2016 in WP 2700/2014 filed by IPA. SPL (C) 2700/2014 filed by IPA was dismissed on 24.10.2016 by the Hon'ble Supreme Court of India in favour of Government/NPPA. The Authority appreciated the efforts taken by PLC and his legal team in pursuing these cases.

11. The Authority also placed on record its appreciation of the work of the Pricing Division of NPPA. NPPA was able to notify prices of 540 scheduled formulations of revised Schedule-I of DPCO 2013 within a span of just 8 months from the date of notification of revised Schedule-I (i.e. 10.3.2016) [vis-a vis 2 years' period taken for ceiling price notifications of 530 Scheduled formulations under original Schedule-I].

12. The meeting ended with a vote of thanks to the Chair.


(Dr. Sharmila Mary Joseph K)
Member Secretary