

मिसिलस - 8(32)/2016/डी.पी./एनपीपीए- डीवी-II

F. No. 8(32)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 164/32/2016/F
Proceeding No : 164/32/2016/F

Minutes of the 164th and 32nd meeting of Authority under DPCO, 2013 held on 02.6.2016 at 11.00 AM.

- I. 1. The 164th overall meeting of the Authority, which is the 32nd under the DPCO, 2013 was held on 02nd June, 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. K.L. Prasad, Member (Ex-Officio), Adviser, Economic Division, Deptt. of Economic Affairs.
- (iii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iv) 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) Smt. Roshni Sohni, Director (M&E/Admn.)
- (iii) Shri A.K. Khurana, Director (Pricing)
- (iv) Shri A.P.S. Sawhney, Director (Overcharging)
- (v) Shri Baljit Singh, Asstt. Director (Pricing)
- (vi) Shri Prasenjit Das, Asstt. Director (Pricing)
- (vii) 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 31st Meeting held on 18.5.2016.

Since no comments were received on the minutes of 163rd and the 31st 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).

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3.1 The Authority discussed in detail the data on 25 formulations and approved the ceiling prices in respect of all the following 25 formulations.

Sl. No.	NLEM Number	Formulation	Strength	Unit for ceiling price	Ceiling Price (Rs.)
1	2.1.2	Diclofenac	50mg Tablet	Per Tablet	1.77
2	2.1.5	Paracetamol	500mg Tablet	Per Tablet	0.83
3	3.2	Cetirizine	10mg Tablet	Per Tablet	1.53
4	5.7	Phenobarbitone	60mg Tablet	Per Tablet	1.64
5	6.2.1.1	Amoxicillin	250mg Capsule	Per Capsule	2.05
6	6.2.1.11	Ceftriaxone	Powder For Injection 250mg	Each Pack	22.90
7	6.2.1.2	Amoxicillin(A)+ Clavulanic Acid (B)	200mg(A)+28.5mg(B) Oral Liquid /5ml	Per ML	1.68
8	6.3.3	Fluconazole	150mg Tablet	Per Tablet	10.99
9	7.2.2	Propranolol	40mg Tablet	Per Tablet	2.59
10	8.1.23	Imatinib	400mg Tablet	Per Tablet	213.32
11	8.3.1	Azathioprine	50mg Tablet	Per Tablet	9.02
12	8.4.1	Allopurinol	100mg Tablet	Per Tablet	1.76
13	8.4.13	Ondansetron	4mg Tablet	Per Tablet	4.35
14	8.4.13	Ondansetron	2mg/ML Injection	Per ML	5.43
15	9.2	Trihexyphenidyl	2mg Tablet	Per Tablet	1.13
16	12.1.7	Metoprolol	25mg Tablet	Per Table	2.88
17	12.1.7	Metoprolol	50mg Tablet	Per Tablet	4.36
18	20.1.2	Pantoprazole	40mg Injection	Each Pack	41.32
19	20.4.2	Hyoscine Butyl Bromide	10mg Tablet	Per Tablet	2.77
20	20.5.1	Bisacodyl	5mg Tab	Per Tablet	0.93
21	21.2.1.1	Ethinylestradiol+ Levonorgestrel	0.03mg+0.15mg Tab	Per Tablet	3.07
22	21.4.1.4	Metformin	500mg Immediate Release Tablet	Per Tablet	1.39
23	21.6.2	Norethisterone	5mg Tablet	Per Tablet	4.75
24	21.7.1	Carbimazole	5mg Tablet	Per Tablet	1.76
25	30.1	Ascorbic Acid (Vitamin C)	500mg Tablet	Per Tablet	0.73

4. Agenda Item no. 4: Representations for Price revision of 'Gentamycin Injection 40mg/ml, Dexamethasone Injection 4mg/ml, Paracetamol Injection 150mg/ml and Tetanus Toxoid injection.

4.1 After detailed discussions, the Authority decided to deliberate upon the matter further on 03.6.2016 at 12.30 PM, after analysing of sales data of the different formulations and the implications of the ongoing litigations.

5. Agenda Item no. 5: Fixation of retail price in respect of new drugs.

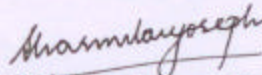
The Authority discussed the following 8 cases of retail price fixation of new drugs falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices of the following under para 5 of the DPCO 2013, as under:

S. No.	Company name/Product name	Approved Price (Rs.)
5(i)	M/s Scott Edil Advance Research Lab. & Education Ltd. (Manufacturer) and M/s Gem Mankind (Marketing company) – Cefixime (as trihydrate) eq. to anhydrous cefixime 200mg, Ofloxacin 200mg – (Cefaclass – O Tablet).	Rs. 9.86/tablet
5(ii)	M/s Apex Lab. Pvt. Ltd. (Manufacturer as well as Marketing company) – Adapalane 0.1% w/w, Hydrous Benzoyl Peroxide eq. to anhydrous Benzoyl Peroxide 2.5% w/w – (Adapalene 0.1% w/w and Benzoyl Peroxide 2.5%w/w Gel).	Rs. 18.10/gm
5(iii)	M/s Innova Captab (Manufacturer) and M/s Leeford Healthcare Ltd., (Marketing company) – Diclofenac sodium 100mg – (Zeldinac 100 SR tablet).	Rs. 4.28/tablet
5(iv)	M/s Ravenbhel Healthcare Pvt. Ltd. (Manufacturer) and M/s Torrent Pharmaceuticals Ltd. (Marketing company) – Gliclazide (as extended release) 30mg + Metformin HCl (as extended release) 500mg – (Azukon M OD 30 tablet).	Rs. 4.96/tablet
5(v)	M/s Ravenbhel Healthcare Pvt. Ltd. (Manufacturer) and M/s Torrent Pharmaceuticals Ltd. (Marketing company) – Gliclazide (as extended release) 60mg + Metformin HCl (as extended release) 500mg – (Azukon M OD 60 tablet).	Rs. 7.98/tablet
5(vi)	M/s Apex Lab. Pvt. Ltd. (Manufacturer as well as the Marketing company) – Dextromethorphan Hydrobromide 10mg + Chlorpheniramine maleate 2mg – (Dextromethorphan Hydrobromide 10mg + Chlorpheniramine maleate 2mg syrup).	Rs. 0.50 per ml
5(vii)	M/s Beta Drugs Pvt. Ltd. (Manufacturer) and M/s Cadila Pharmaceuticals Ltd. (Marketing company) – Paclitaxel 100mg (Human Albumin) – [Paclitaxel (Protein bound particle) for injectable suspension].	Rs. 11590.00 per vial
5(viii)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Magnet Labs. Pvt. Ltd. (Marketing company) – Escitalopram Oxalate eq. to Escitalopram 10mg and Clonazepam 0.5mg – (Megapose-Plus New tablet).	Rs. 8.62 per tablet

6. **Agenda Item no. 6: Review order of DOP on the applications of various pharma companies against S.O. 3127(E) dated 10.12.2014 for revision of ceiling prices of IV Fluids.**

6.1 Preliminary discussion on the matter was held. The Authority decided to meet again on 03.6.2016 at 12.30 PM to discuss this issue further, after analysing the DPCO, 1995 price fixation details also.

7. The meeting ended with vote of thanks to the chair.


(Dr. Sharmila Mary Joseph K)
Member Secretary