

गोपनीय: Confidential

मिसिलस.- 8(35)/2016/डी.पी./एनपीपीए- डीवी-II

F. No. 8(35)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 166/35/2016/F

Proceeding No : 166/35/2016/F

Minutes of the 167th and 35th meeting of Authority under DPCO, 2013 held on 17.8.2016 at 11.00 AM.

- I. 1. The 167th overall meeting of the Authority, which is the 35th under the DPCO, 2013 was held on 17th August, 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.Chandrashekhar, 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 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 34th Meeting held on 29.7.2016.

Since no comments were received on the minutes of 166th and the 34th 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 discussed in detail the data on 21 formulations and approved the ceiling prices in respect of the following 21 formulations.

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S. N O.	UNIQUE NO. AS PER NLEM	NAME OF THE FORMULATION/ COMPOSITIONS	STRENGTH	DESCRIPTI ON	PACK SIZE	APPROVED CEILING PRICE under NLEM, 2015 (Rs.)
Common Cases						
1	1.3.1	ATROPINE	0.6mg/ml injection	Injection	Per ML	3.73
2	2.1.3	IBUPROFEN	200 mg tablet	Tablet	Per Tablet	0.35
3	2.1.3	IBUPROFEN	400 mg tablet	Tablet	Per Tablet	0.65
4	4.2.8	NEOSTIGMINE	0.5 mg/ml injection	Injection	Per ML	4.04
5	5.1	CARBAMAZEPINE	100 MG/5ml oral liquid	Oral Liquid	Per ML	0.18
6	5.3	DIAZEPAM	5 mg suppository	Suppository	Per Suppository	5.55
7	5.7	PHENOBARBITONE	200mg/ml injection	Injection	Per ML	17.78
8	6.2.2.8	NITROFURANTOIN	100 mg tablet	Tablet	Per Tablet	6.71
9	6.2.3.3	RIFAMPICIN	300 mg capsule	Capsule	Per Capsule	3.37
10	6.2.3.3	RIFAMPICIN	150 mg capsule	Capsule	Per Capsule	1.82
11	6.2.4.13	RIFAMPICIN	450 mg capsule	Capsule	Per Capsule	4.43
12	6.5.3.1.6	PRIMAQUINE	7.5mg tablet	Tablet	Per Tablet	1.96
13	8.1.23	IMATINIB MESYLATE	100 mg tablet	Tablet	Per Tablet	71.66
14	8.1.30	PROCARBAZINE	50 mg capsule	Capsule	Per Capsule	30.76
15	8.2.4	TAMOXIFEN	10 mg tablet	Tablet	Per Tablet	2.39
16	8.2.4	TAMOXIFEN	20 mg tablet	Tablet	Per Tablet	2.7
17	26.1.4	MISOPROSTOL	100 mcg tablet	Tablet	Per Tablet	8.08
18	28.1.5	SALBUTAMOL	2 mg tablet	Tablet	Per Tablet	0.14838
New Cases						
19	6.4.3.2.1	EFAVIRENZ	600 mg tablet	Tablet	Per Tablet	63.19
20	6.4.3.4.4	RITONAVIR	100 mg tablet	Tablet	Per Tablet	26.92
21	6.5.3.1.6	PRIMAQUINE	15 mg tablet	Tablet	Per Tablet	4.26

The Authority also noted that in case of some common formulations, some companies were selling their products at prices higher than the ceiling prices fixed by NPPA earlier. It was decided that action will be taken against these companies for non-compliance of ceiling prices fixed by NPPA earlier and it should be reported to Authority in the next meeting as part of Action Taken Report.

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

4.1 The Authority discussed the following 13 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:

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S. No.	Company name/Product name	Approved Retail Price (Rs.)
4(i)	M/s Tristar Formulations Pvt. Ltd. (Manufacturer) and M/s Lupin Ltd. (Marketing company) - Amlodipine 5mg and Metoprolol tartrate 25mg ER tablet- (Starpress-AM XL 25 tablet).	Rs. 4.80/tablet
4(ii)	M/s German Remedies Ltd. (Manufacturer as well as Marketing company) - Amlodipine 5mg and Metoprolol tartrate 25mg ER tablet- (Amlodac M25 tablet).	Rs. 4.80/tablet
4(iii)	M/s Savi Pharma (Manufacturer) and M/s Aikem Lab. Ltd. (Marketing company) and - Glimepiride 4mg (Glucoryl 4mg tablet).	Rs. 6.00/tablet
4(iv)	M/s Cadila Healthcare Ltd. (Manufacturer as well as Marketing company) - r-HuErythropoietin (r-HuEPO) 4000 IU - (Renocrit 4000 injection).	Rs. 1237.23/peck
4(v)	M/s Cadila Healthcare Ltd. (Manufacturer as well as Marketing company) - Zoledronic Acid 4mg vial - (Zoledronic Acid infusion 4mg/100ml).	Rs. 3609.13/peck
4(vi)	M/s Emcure Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) - Doxorubicin HCL 2mg/ml - (Doxorubicin HCL Pegylated Liposomal 2mg injection).	Rs. 723.93/ml
4(vii)	M/s Windas Biotech Ltd. (manufacturer) and M/s Emcure Pharmaceuticals Ltd., (marketing company) - Telmisartan 40mg and Chlorothalidone 6.25mg - (Telmisartan 40mg and Chlorothalidone 6.25mg tablet).	Rs. 7.73/tablet
4(viii)	M/s Inventia Healthcare Pvt. Ltd. (Manufacturer) and M/s Jubilant Life Science Ltd. (Marketing company) - Metformin HCl 500mg, Voglibose 0.2mg and Glimepiride 2mg - (Metformin HCl SR, Voglibose and Glimepiride tablet).	Rs. 90.48/10 tablets
4(ix)	M/s Inventia Healthcare Pvt. Ltd. (Manufacturer) and M/s Jubilant Life Science Ltd. (Marketing company) - Metformin HCl 500mg, Voglibose 0.2mg and Glimepiride 1mg - (Metformin HCl SR, Voglibose and Glimepiride tablet).	Rs. 71.43/10 tablets
4(x)	M/s Torrent Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) - Paroxetine HCl 25mg and Clonazepam 0.5mg - (Clonotril P 25mg capsule).	Rs. 12.50/capsule
4(xi)	M/s Torrent Pharmaceuticals Ltd. (Manufacturer as well as Marketing company) - Paroxetine HCl 25mg and Clonazepam 0.5mg - (Clonotril P 12.5mg capsule).	Rs. 10.27/capsule
4(xii)	M/s Enicar Pharmaceuticals Pvt. Ltd. (Manufacturer) and M/s Group Pharmaceuticals Ltd (Marketing company) - Phenylephrine HCL 5mg, Chlorpheniramine maleate 0.5mg, Paracetamol 125mg, Sodium Citrate 60mg and Menthol 1mg - (Sudin Kid+ Syrup).	Rs. 0.59/ml
4(xiii)	M/s Pharma Force Lab. (Manufacturer) and M/s Lifestar Pharma Pvt. Ltd. (Marketing company) - Phenylephrine HCL 5mg, Chlorpheniramine maleate 0.5mg, Paracetamol 125mg, Sodium Citrate 60mg and Menthol 1mg - (Nablok-New Syrup).	Rs. 0.59/ml

The Authority decided that a statement is to be prepared showing the details of cases where retail price was fixed on monopoly basis since promulgation of DPCO, 2013; and the current prices of such products and details of other brands in respect of these products to see whether the existing system of price fixation in such cases is actually helping in setting competition.

5. Agenda Item no. 5: Representation for Price revision of 'Cyclosporine 100mg/ml oral liquid' notified vide S.O. 1561(E) dated 27.4.2016.

5.1 This case was discussed in detail and the Authority approved the revised ceiling price of Cyclosporine oral liquid 100mg/ml at Rs. 84.11/ml on the basis of representation received from M/s Panacea Biotech Ltd.

6. Agenda Item no. 6: Review orders passed by Dept. of Pharmaceuticals (DOP) on 22.7.2016 in respect of review applications of Dr. Reddy's Labs. Ltd. and M/s J.B. Chemicals & Pharmaceuticals Ltd.

6.1 The Authority decided to call for advice from the Principal Legal Consultant in respect of the specific legal points raised in the DOP's order and how to ensure compliance since there was ambiguity in the order regarding Para 20(1).

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


(Dr. Sharmila Mary Joseph K)
Member Secretary