

मिसिलस - 8(30)/2016/डी.पी./एनपीपीए- डीवी-II

F. No. 8(30)/2016/DP/NPPA-Div. II

कार्यवाहीस. : 162/30/2016/F

Proceeding No : 162/30/2016/F

Minutes of the 162<sup>nd</sup> and 30<sup>th</sup> meeting of Authority under DPCO, 2013 held on 09.5.2016 at 11.00 AM.

- I. 1. The 162<sup>th</sup> overall meeting of the Authority, which is the 30<sup>th</sup> under the DPCO, 2013 was held on 09<sup>th</sup> May, 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 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 29<sup>th</sup> Meeting held on 27.4.2016.**

Since no comments were received on the minutes of 161<sup>st</sup> and the 29<sup>th</sup> 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 54 formulations and approved the ceiling prices in respect of all the following 54 formulations

**A. NLEM, 2015 (Revised Schedule-I)**

I. Newly Added Formulations					
S.No	NLEM Number	Formulation Name	Dosage Form & Strength	Unit for ceiling price	Ceiling Price
1	1.2.4	Prilocaine (A) + Lignocaine (B)	Cream 2.5% (A) + 2.5% (B)	Per GM	18.97
2	3.2	Cetirizine	Oral liquid 5 mg/5 ml	Per ML	0.55
3	3.5	Hydrocortisone	Powder for Injection 100mg	Each Pack	34.63
4	5.4	Levetiracetam	Injection 100mg/ml	Per ml	20.25
5	6.2.2.1	Azithromycin	Oral Liquid 200mg/5ml	Per ml	2.85
6	6.2.1.8	Cefixime	Oral liquid 100 mg/5 ml	Per ML	1.99
7	6.2.1.8	Cefixime	Oral liquid 50 mg/5 ml	Per ML	1.34
8	6.4.4.2	Pegylated interferon alfa 2b	Injection 100mcg	Each Pack	14515.85
9	6.4.4.2	Pegylated interferon alfa 2b	Injection 80mcg	Each Pack	11605.01
10	8.1.34	Trastuzumab	Injection 440 mg/50 ml	Each Pack	55812.29
11	14.1.1	Clotrimazole	Cream 1%	Per GM	2.35
12	14.2.4	Povidone iodine	Solution 7.5%	Per ML	0.73
13	19.3	Clotrimazole	Drops 1%	Per ML	2.81
14	24.2	Caffeine	Oral Liquid 20mg/ml	Per ML	197.80
15	27.1.3	Haloperidol	Oral liquid 2 mg/ 5ml	Per ML	1.91
16	28.1.5	Salbutamol	Respirator solution for use in nebulizer 5mg/ml	Per ML	0.66
17	28.1.6	Tiotropium	Inhalation (MDI) 18 mcg/dose	Per MDI	2.29
18	28.1.6	Tiotropium	Inhalation (MDI) 9 mcg/dose	Per MDI	2.16
19	29.4	Potassium chloride	Oral liquid 500 mg/5 ml	Per ML	0.26
20	30.4	Cholecalciferol	Oral liquid 400 IU/ml	Per ML	2.19

II. Common Formulations					
S.No	NLEM Number	Formulation Name	Dosage Form & Strength	Unit for ceiling price	Ceiling Price
1	4.2.9	Penicillamine	250mg Capsule	Per Capsule	13.23
2	5.8	Phenytoin	50mg Tab	Per Tablet	0.70
3	6.2.1.11	Ceftriaxone	Powder for injection 1gm	Each Pack	47.95
4	6.2.2.1	Azithromycin	Tablet 500 mg	Per Tablet	17.83
5	6.2.2.1	Azithromycin	Tablet 250 mg	Per Tablet	9.06
6	6.2.2.2	Ciprofloxacin	Tablet 250 mg	Per Tablet	1.62
7	6.2.2.2	Ciprofloxacin	Tablet 500 mg	Per Tablet	3.30
8	8.1.18	Doxorubicin	Injection 2mg per ML	Per ML	33.31
9	12.1.2	Clopidogrel	Tablet 75 mg	Per Tablet	6.44
10	12.3.1	Amlodipine	5mg Tablet	Per tablet	2.33
11	22.3.2.1	Antirabies Vaccine	Injection	Each Pack	304.08
12	28.1.3	Hydrocortisone	Injection 100mg	Each Pack	34.63

**B. NLEM 2015 - Plus Schedule-I**

I. Newly Added Formulations					
S.No	NLEM Number	Formulation Name	Dosage Form & Strength	Unit for ceiling price	Ceiling Price
1	6.2.1.6	Cefadroxil	500mg Capsule	Per Capsule	6.64
2	6.2.4.2	Cycloserine	250mg Tabs	Per Tablet	43.31
3	7.2.2	Propranolol	80mg Capsule	Per Capsule	5.35
4	8.1.32	Temozolomide	20mg Tabs	Per Tablet	347.68
5	8.1.32	Temozolomide	100mg Tabs	Per Tablet	1435.03
6	8.1.32	Temozolomide	250mg Tabs	Per Tablet	3551.86
7	8.4.9	Loperamide	2mg Capsule	Per Capsule	3.32
8	8.4.14	Tramadol	100mg Tablet	Per Tablet	18.25
9	12.1.3	Diltiazem	90mg Capsule	Per Capsule	8.91
10	12.1.7	Metoprolol	50mg Capsule	Per Capsule	5.98
11	12.1.7	Metoprolol	25mg Capsule	Per Capsule	3.92
12	12.3.7	Ramipril	2.5mg Capsule	Per Capsule	4.38
13	12.3.7	Ramipril	5mg Capsule	Per Capsule	6.85
14	27.2.1.3	Fluoxetine	10mg Tablet	Per Tablet	2.31
15	27.2.1.3	Fluoxetine	40mg Tablet	Per Tablet	4.95
16	27.2.1.3	Fluoxetine	60mg Tablet	Per Tablet	6.86
17	27.4.1	Clomipramine	75mg Tablet	Per Tablet	13.32
18	27.4.1	Clomipramine	25mg Tablet	Per Tablet	5.15
19	27.4.1	Clomipramine	10mg Tablet	Per Tablet	2.33
20	30.4	Cholecalciferol	60000IU Capsule	Per Capsule	26.09
21	30.4	Cholecalciferol	1000 IU Capsule	Per Capsule	4.42

II. Common Formulations					
S.No	NLEM Number	Formulation Name	Dosage Form & Strength	Unit for ceiling price	Ceiling Price
1	6.5.3.1.5	Clindamycin	Tablet 300mg	Per Tablet	13.56

#### 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 Price (Rs.)
4(i)	M/s Mascot Health Series Pvt. Ltd. is the Manufacturer and M/s Wallace Pharmaceuticals Pvt. Ltd. (marketing company) – Glimepiride 1mg + Metformin HCl 1000mg (SR) – (Walaphage G1 Forte tablet).	5.93/tablet
4(ii)	M/s Mascot Health Series Pvt. Ltd. is the Manufacturer and M/s Wallace Pharmaceuticals Pvt. Ltd. (marketing company) – Glimepiride 2mg + Metformin HCl 1000mg (SR) – (Walaphage G2 Forte tablet).	7.50/tablet
4(iii)	M/s Chiros Phama is the Manufacturer and M/s Biochem Pharmaceuticals Industries Ltd., (marketing company) – Amoxycilin trihydrate eq. to amoxicillin 400mg + Potassium Clavulanate diluted eq. to Clavulanic acid 57mg – Ampilox CV 475 Syrup).	3.03/ml
4(iv)	M/s Glenmark Pharmaceuticals Ltd. is the Manufacturer and M/s Unichem Lab. Ltd. (marketing company) – Teneiglipitin Hydrobromide Hydrate eq. to Teneiglipitin 20mg and Metformin HCl 500mg (SR) – (Teneiglipitin + Metformin HCL tablet).	111.43/10 tablets

4(v)	M/s Glenmark Pharmaceuticals Ltd. is the Manufacturer and M/s Indoco Remedies Ltd. (marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 500mg (SR) – (J-Ring M tablet).	111.43/10 tablets
4(vi)	M/s Glenmark Pharmaceuticals Ltd. is the Manufacturer and M/s Micro Labs. Ltd. (marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 500mg (SR) – (Tenepride M 500 tablet).	111.43/10 tablets
4(vii)	M/s Glenmark Pharmaceuticals Ltd. is the Manufacturer and M/s Alembic Pharmaceuticals Ltd. (marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 500mg (SR) – (Teneligliptin + Metformin HCL tablet).	111.43/10 tablets
4(viii)	M/s Glenmark Pharmaceuticals Ltd. is the Manufacturer and M/s Torrent Pharmaceuticals Ltd. (marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 500mg (SR) – (Afoglip M500 tablet).	111.43/10 tablets
4(ix)	M/s Glenmark Pharmaceuticals Ltd. is the Manufacturer and M/s Intas Pharmaceuticals Ltd. (marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 500mg (SR) – (Teneligliptin + Metformin HCL tablet).	111.43/10 tablets
4(x)	M/s Glenmark Pharmaceuticals Ltd. is the Manufacturer and M/s Centaur Pharmaceuticals Pvt. Ltd. (marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 500mg (SR) – (Ten20M 500 tablet).	111.43/10 tablets
4(xi)	M/s Glenmark Pharmaceuticals Ltd. is the Manufacturer and M/s Wockhardt Ltd. (marketing company) – Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg and Metformin HCl 500mg (SR) – (Inogla M500 tablet).	111.43/10 tablets

4.2 The Authority noted that products listed at S.No. 4(iv) to 4(xi) above are manufactured by M/s Glenmark while marketed by different companies. The companies have claimed different retail prices. The Authority discussed and decided that the price claimed by M/s Unichem Lab. at Rs. 111.43 for pack of 10 tablets, being the lowest (among the claims made in the relevant applications) can be applied to all the relevant eight cases as mentioned above.

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

*Sharmila Mary Joseph*

(Dr. Sharmila Mary Joseph K)  
Member Secretary