गोपनीय: Confidential

मिसिलस.- 8(45)/2017/डी.पी/एनपीपीए-डीवी-II

F. No. 8(45)/2017/DP/NPPA-Div. II

कार्यवाहीस. : 177/45/2017/F

Proceeding No : 177/45/2017/F

Minutes of the 177th and 45th meeting of Authority under DPCO, 2013 held on 23.5.2017 at 11.00 A.M.

I. 1. The 177th overall meeting of the Authority, which is the 45th under the DPCO, 2013 was held on 23rd May, 2017 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) Shri Umesh Dongre, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
(iii) Shri Arun Kumar, Adviser, Deptt. of Economic Affairs, Ministry of Finance.
(iv) Shri R. Chadrashekhar, Deputy Drug Controller, Deptt. of Health & Family Welfare (representing DCG(I)).

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 44th Meeting held on 26.4.2017.

1.1 The Authority confirmed the minutes of the overall 176th and the 44th Meeting held on 26.4.2017 under DPCO, 2013.

2. Agenda Item no. 2: Action Taken Report

2.1 Noted.

2.2 The Authority discussed DoP's OM dated 20.4.2017 regarding considering the PTR of only such formulations/brands that have more than 1% market share for working out ceiling prices of scheduled medicines. The Authority also considered DoP's previous orders No.34015/71/2013-PI.I dated 19th February, 2014 and No.31015/33/2014-PI.I dated 5th November, 2014 in which NPPA's present policy was endorsed by Government and reviews were rejected. The Authority also noted that NPPA has been following the present policy in order to stop any chance of price manipulation by several drug manufacturers by launching several brands of same formulation at different prices. This issue of concern has also been raised during the discussions on formulation of new Pharmaceutical Policy by the Government. Deviating from this principle shall be re-enforcing a practice. In the given context the Authority decided that since matter is of great public importance, a formal letter of request may be sent to DoP alongwith the copies of previous relevant review orders and other documents with a request for reconsideration of its review orders. It was also decided
that the ceiling prices in respect of all the formulations may be done, including the 3 (three) formulations viz. Snake venom antiserum- Lyophilized polyvalent, Heparin 5000 IU/ml Injection and IUD containing Copper- as licensed (approved in the previous 44th meeting but pending for notification)"may also be notified as per NPPA's consistent policy of considering the 'least price' option (among the three alternatives for determining 1% market share, for working out ceiling prices) in consumers' interest and as per the previous orders of the Government.

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 the following 21 formulations and approved the same.

S. NO.	UNIQUE NO. AS PER NLEM	NAME OF THE FORMULATION/ COMPOSITIONS	DOSAGE FORM & STRENGTH	UNIT FOR PRICE	Approved CEILING PRICE UNDER NLEM, 2015 (Rs.)
1	2	3	4	5	6
A. Common Formulations					
Section 1–Anesthetic agents					
1.3–Preoperative medication and sedation for short term procedures					
1	1.3.4	Morphine	Injection 10 mg/ml	PER ML	22.47
Section 2–Analgesics, antipyretics, non steroidal anti inflammatory medicines, medicines used to treat gout and disease modifying agents used in rheumatoid disorders					
2.2–Opioid analgesics					
2	2.2.2	Morphine	Tablet 10 mg	Per Tablet	5.04
Section 22–Immunologicals					
22.3.1–For universal immunisation					
3	22.3.1.3	DPT vaccine		Per 0.5 ML	12.85
4	22.3.1.4	Hepatitis B vaccine		Per ML	71.06
Section 29–Solutions correcting water, electrolyte disturbances and acid-base disturbances					
5	29.1	Glucose	Injection 10%-500ML	Each Pack	26.58
6	29.1	Glucose	Injection 10%-1000ML	Each Pack	24.43
B. New Formulations					
Section 1–Anesthetic agents					
1.3–Preoperative medication and sedation for short term procedures					
7	1.3.4	Morphine	Injection 15 mg/ml	PER ML	28.04
Section 5–Anticonvulsants/ Antiepileptics					
8	5.9	Sodium valproate	CR Tablet 500 mg	Per Tablet	8.82
9	5.9	Sodium valproate	CR Tablet 300 mg	Per Tablet	5.73
Section 11–Blood products and Plasma substitutes					
11.3–Plasma fractions for specific use					
10	11.3.2	Coagulation factor VIII	Powder for Injection 500 IU	Each Pack	8,316.70
Section 18–Diuretics					
11	18.4	Spironolactone	Tablet 50 mg	Per Tablet	3.60
C. Common Formulations (Explanation to Schedule-I)					
Section 6–Anti infective medicines					
6.2–Antibacterials					
6.2.3–Antileprosy medicines					
12	6.2.3.3	Rifampicin	Tablet 150 mg	Per Tablet	1.53
6.3–Antifungal medicines					
13	6.3.3	Fluconazole	Capsule 150 mg	Per Capsule	17.55
D. New Formulations (Explanation to Schedule-I)					
2.1– Non-opioid analgesics, antipyretics and nonsteroidal anti-inflammatory medicines					
14	2.1.2	Diclofenac	Capsule 50 mg	Per Capsule	0.58

15	2.1.3	Ibuprofen	Capsule 400 mg	Per Capsule	1.00
14.1–Antifungal medicines					
16	14.1.1	Clotrimazole	Lotion 1%	PER ML	3.39
14.5–Scabicides and pediculicides					
17	14.5.1	Permethrin	Cream 1%	Per GM	1.52
18	14.5.1	Permethrin	Gel 5%	Per GM	1.38
19	14.5.1	Permethrin	Lotion 5%	PER ML	0.92
21.5–Ovulation Inducers					
20	21.5.1	Clomiphene	Capsule 50 mg	Per Capsule	28.97
Section 22–Immunologicals					
22.3.1–For universal immunisation					
21	22.3.1.2	DPT + Hib + Hep B vaccine		Per 0.1 ML	72.874

4. Agenda Item no. 4: Review orders passed by DoP in respect of M/s Sanofi India Ltd., M/s Wockhardt Ltd., M/s Abbott Healthcare Ltd., M/s Neon Lab. Ltd. and M/s IPCA Lab. Ltd. for price fixation/revision.

4.1 Noted and approved.

5. Agenda Item no. 5: Price fixation of new drug under para 5 of DPCO, 2013.

5.1 The Authority directed Pricing Division to give complete status of price approval of 'new drug' cases in the Agenda notes from the next meeting onwards.

5.2 The Authority discussed the earlier decision taken in the 36th meeting (held on 14.9.2016) that in cases, where NPPA had notified the retail price for formulations with same composition earlier under DPCO, 2013 at any period more than a year ago, 10% per annum increase on the retail price fixed earlier will be considered. Authority took note of the fact that 201 new drugs were launched in the market without price approval and expressed grave concern on the same. The growing tendency of drug manufacturers to do some 'tweaking' of scheduled drugs and launch 'new drug', to come out of price control, needs to be discouraged. The Authority asked Monitoring Division to check the MAT value and volumes of all the drugs which are common to NLEM-11 and NLEM-15 so as to ascertain the exact extent of such migration. It was also considered that the 'new drugs' have the main component of some 'scheduled drug' in all cases, and it needs to be treated substantially as scheduled drug and it should not be treated at par with the 'non-scheduled drug' which enjoy the benefit of 10% increase per annum. The options of giving WPI based price increase or no price increase were also considered but finally Authority decided that this issue needs to be discussed in the next

meeting of the Authority along with all relevant statistical details and till then existing policy may continue. Authority, however, decided that in all future cases of approval of new drugs, the Pricing Division should also examine and submit following information along with already prescribed format for the approval of the Authority.

(a) The existing trade margins in the particular formulation which is proposed to be the component of the 'new drug'.
(b) Status on whether there is a 'monopoly' in the segment of the particular combination.
(c) The status of MAT and volumes of the particular scheduled drug and its overall availability.

With these directions for future compliance, the Authority approved following new drug prices:

5.3 The Authority discussed all the 7 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, (except the case at serial no 5(vii)) which has been deferred for the next meeting.

S. No.	Company name/Product name	Approved Retail Price (Rs.)
(i)	M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Jubilant Life Sciences Ltd. (Marketing company) - Telmisartan 40mg + Metoprolol succinate eq. to Metoprolol Tartrate 25mg (as extended release) - (Telmijub Beta 25).	7.95 per Tablet
(ii)	M/s Pure and Cure Healthcare Pvt. Ltd. (Manufacturer) and M/s Jubilant Life Sciences Ltd. (Marketing company) - Telmisartan 40mg + Metoprolol succinate eq. to Metoprolol Tartrate 50mg (as extended release) - (Telmijub Beta 50).	9.55 per Tablet
(iii)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Glenmark Pharmaceuticals Ltd. (Marketing company) - Glimepiride 1mg, Voglibose 0.2mg and Metformin HCl 500mg - (Glimepiride + Voglibose + Metformin SR Tablet).	71.43/10 Tablets
(iv)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Glenmark Pharmaceuticals Ltd. (Marketing company) - Glimepiride 2mg, Voglibose 0.2mg and Metformin HCl 500mg - (Glimepiride+ Voglibose + Metformin SR Tablet).	90.48/10 Tablets
(v)	M/s Windlas Biotech Ltd. (Manufacturer) and M/s Abbott Healthcare Pvt. Ltd. (Marketing company) -Telmisartan 80mg, Chlorthalidone 12.5mg - (Telpres CT 80 Tablet).	7.00 per Tablet
(vi)	M/s The Madras Pharmaceuticals (Manufacturer) and M/s Blue Cross Lab. Pvt. Ltd. (Marketing company) - Diclofenac Diethylamine 1.16% w/w (eq. to Diclofenac Sodium 1% w/w), Linseed Oil 3% w/v, Methyl Salicylate 10% w/w and Menthol 5% w/w - (DICLOTAL+ Gel).	2.32 per gram

6. **Agenda Item no. 6: Form-I application submitted by M/s Synokem Pharmaceuticals Ltd. (Manufacturer) and M/s Torrent Pharmaceuticals Ltd. (Marketing company) – Rosuvasttin 10mg and Clopidogrel 75mg – (Rozuplatt 10 Capsule) under DPCO, 2013.**

6.1 The Authority noted and approved the retail price of Rs. 13.94 per capsule for notification.

7. Agenda Item no. 7: Minutes of the 4th (continued) meeting of Committee of Experts under para 11(3& 4) held on 02.5.2017 at 10:00 AM in NPPA.

7.1 Noted.

8. Agenda Item no. 8: Minutes of the 8th meeting of Standing Committee of Experts held on 02.5.2017 and 04.5.2017 under Para 15 of the DPCO 2013.

8.1 Noted.

8(a). Agenda Item no. 8(a): Approval for Retail Price of Rabishield Rabies Human Monoclonal Antibody (rDNA) in 250IU(2.5ml) and 100IU(2.5ml) pack of M/s Serum Institute of India Ltd.

8(a)(i) The Authority deferred the issue for the next meeting.

8(b). Agenda Item no. 8(b): Approval for Ceiling Price of Paracetamol Injection 150mg/ml of 0.5ml, 1ml, 3ml, 4ml, 5ml and 7ml packs.

8(b)(i) The Authority deliberated the issue in detail and approved the ceiling prices of 0.5ml, 1ml, 3ml, 4ml, 5ml and 7ml packs of Paracetamol Injection 150mg/ml, as detailed below:-

Formulation	Pack-size	Approved Ceiling Prices (Rs.)
Paracetamol 1.5% w/v (Paracetamol 150mg/ml)	0.5 ml (or 75mg)	2.90
	1.0 ml (or 150mg)	3.97
	3.0 ml (or 450mg)	8.24
	4.0 ml (or 600mg)	10.37
	5.0 ml (or 750mg)	12.51
	7.0 ml (or 1050mg)	16.78

The Authority endorsed the recommendations of the Committee of Experts that as paracetamol 150mg/ml injection is a scheduled formulation listed at Section 2.1.5 of Schedule-I of DPCO, 2013, its ceiling price could be fixed on pack- size basis, in consumer interest.

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

9.1 The Authority noted with satisfaction that most of the review orders (61 under NLEM, 2015) have been complied with and remaining will be completed as soon as possible.

9.2 The Authority also directed that as per NPPA's OM no. 19(119)/2014/Div-II/NPPA dated 01.5.2017 regarding formulations which shifted to non-scheduled category, the Overcharging Division may take action for effecting recovery of overcharged amount, if any, from the companies concerned, upto 01.5.2017.

10. Agenda Item no. 10: SOP for handling cases where pharmaceuticals companies have launched new drugs Without Price Approval (WPA) under Para 15 of DPCO, 2013.

10.1 Noted.

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

Sharmilajoseph

(Dr. Sharmila Mary Joseph K)
Member Secretary