

मिसिलस.- 8(42)/2017/डी.पी/एनपीपीए-डीवी-II

F. No. 8(42)/2017/DP/NPPA-Div. II

कार्यवाहीस. : 174/42/2017/F

Proceeding No: 174/42/2017/F

Minutes of the 174<sup>th</sup> and 42<sup>nd</sup> meeting of Authority under DPCO, 2013 held on 09.3.2017 at 11.00 A.M.

- I. 1. The 174<sup>th</sup> overall meeting of the Authority, which is the 42<sup>nd</sup> under the DPCO, 2013 was held on 09 March, 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 G.S. Negi, Adviser (Price, Money & Banking Unit), Deptt. of Economic Affairs, Ministry of Finance.
- (iii) Shri Devendra Kumar, Adviser (Cost), Deptt. of Expenditure, Ministry of Finance.
- (iv) Shri R. Chadrashekhhar, 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. Shri A.P.S. Sawhney, Director (Overcharging)
- iii. Smt. Roshni Sohni Director (M&E)
- iv. Shri Baljit Singh, Asstt. Director (Pricing)
- v. Shri Prasenjit Das, Asstt. Director (Pricing)

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 41<sup>st</sup> Meeting held on 13.02.2017.**

The Authority confirmed the minutes of the overall 173<sup>rd</sup> and the 41<sup>st</sup> Meeting held on 13.02.2017 under DPCO, 2013.

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 and calculation sheets of 18 formulations at the meeting. The Authority approved the ceiling prices in respect of following 18 formulations.

*Sharmilajoseph*



3.2 The Authority approved the ceiling prices in respect of following 18 formulations:-

S. NO.	UNIQUE NO. AS PER NLEM	NAME OF THE FORMULATION/ COMPOSITIONS	STRENGTH	Dosage Form	Unit for Ceiling Price	Approved ceiling price under NLEM, 2015 (Rs.)
<b>A. Common Cases</b>						
<b>Section 1-Anesthetic agents</b>						
<b>1.2-Local anesthetics</b>						
1	1.2.1	Bupivacaine	0.5% with 7.5% glucose	Injection	Per ML	5.77
2	1.2.2	Lignocaine	Topical forms 2-5%	Injection	Per GM or Per ML	0.97
<b>Section 6-Anti infective medicines</b>						
<b>6.3- Antifungal medicines</b>						
3	6.3.1	Amphotericin B – Conventional	50 mg	Powder for Injection	Each Pack	275.62
4	6.3.1	Amphotericin B – Lipid/ Liposomal	50 mg	Powder for Injection	Each Pack	3,328.61
<b>Section 12-Cardiovascular medicines</b>						
<b>12.1-Medicines used in angina</b>						
5	12.1.1	Acetylsalicylic Acid	100 mg	Tablet	Per Tablet	0.16539
<b>Section 12-Cardiovascular medicines</b>						
<b>12.2-Antiarrhythmic medicines</b>						
6	12.2.5	Verapamil	2.5 mg/ml	Injection	Per ML	1.08
7	12.2.5	Verapamil	80 mg	Tablet	Per Tablet	1.28
8	12.2.5	Verapamil	40 mg	Tablet	Per Tablet	0.70
<b>12.3-Antihypertensive medicines</b>						
9	12.3.6	Methyldopa	250 mg	Tablet	Per Tablet	2.26
<b>Section 14-Dermatological medicines (Topical)</b>						
<b>14.3-Anti-inflammatory and antipruritic medicines</b>						
10	14.3.2	Calamine	(As per IP)	Lotion	Per ML	0.78
<b>Section 18-Diuretics</b>						
11	18.1	Furosemide	40 mg	Tablet	Per Tablet	0.45726
12	18.1	Furosemide	10 mg/ ml	Injection	Each Pack	1.01
13	18.4	Spironolactone	25 mg	Tablet	Per Tablet	1.77
<b>Section 30-Vitamins and minerals</b>						
14	30.9	Vitamin A	50000 IU/ml	Injection	Per MI	1.77
<b>B. New Formulation</b>						
<b>Section 6-Anti infective medicines</b>						
<b>6.3- Antifungal medicines</b>						
15	6.3.4	Griseofulvin	375 mg	Tablet	Per Tablet	4.00
<b>Section 12-Cardiovascular medicines</b>						
<b>12.3-Antihypertensive medicines</b>						
16	12.3.6	Methyldopa	500 mg	Tablet	Per Tablet	4.33



Section 22-Immunologicals						
22.2-Sera and immunoglobulins (Liquid/ Lyophilized)						
17	22.2.6	Human Normal Immunoglobulin		Injection	Per ML	137.27
<b>C. Common Formulations (Explanation to Schedule-I) - NIL</b>						
<b>D. New Formulations (Explanation to Schedule-I)</b>						
Section 30-Vitamins and minerals						
18	30.9	Vitamin A	50000 IU	Tablet	Per Tablet	0.66

3.2.1 Methyldopa 500mg tablet:- The Authority examined the draft calculation sheet of Methyldopa 500mg tablet and the review order No. 31015/5/2016-PI.I dated 05.01.2017. The Authority noticed that the retail price of this formulation had been fixed on 29.3.2016 as Rs. 4.46 per tablet. The Authority decided to consider the same price as ceiling price of this formulation. After adjustment of WPI of (-) 2.7105%, this was approved as Rs. 4.33/tablet.

3.2.2 Human Normal Immunoglobulin:- The representation of M/s Reliance Life Sciences regarding the draft ceiling price of Rs. 128.84/ml was examined. It was noted that one formulation 'Histoglob' had a different composition compared to the subject formulation. The Authority decided to exclude Histoglob from the calculation of ceiling price of Human Normal Immunoglobulin. Accordingly, the Authority approved the ceiling price of Human Normal Immunoglobulin as Rs. 137.27/ml.

3.2.3 Amphotericin B (Lipid/Liposomal Injection):- M/s Abbott Healthcare Private Limited represented against the draft working price requesting separate ceiling price for Lipid and Liposomal forms of Amphotericin B. The Authority discussed the same and rejected the application as the classification of a) Conventional and b) Lipid/Liposomal was in line with NLEM, 2015 and revised Schedule-I of DPCO 2013. The Authority observed that there was no need for further classification. Accordingly, the Authority approved the ceiling price of Amphotericin B (Lipid/Liposomal Injection) as Rs. 3328.61/pack.

**4. (i) Agenda Item no. 4:**

(i) Minutes of the 4<sup>th</sup> meeting of Committee of Experts under para 11(3&4) held on 30.01.2017 at 11:00 AM in NPPA

4.1 Noted.

4.2 (ii) Minutes of the 7<sup>th</sup> meeting of Standing Committee of Experts held on 30.01.2017 under Para 15 of the DPCO 2013

4.1 Noted.

**5. Agenda Item no. 5: Representation received from FICCI on revised guidelines on discontinuation of scheduled formulations under para 21(2) of DPCO, 2013.**

5.1 The Authority examined the matter and observed that the guidelines are within the ambit of DPCO, 2013 and do not need any modification/amendment.

**6. Agenda Item no. 6: Internal guideline for initiating prosecution against the company launching new drugs Without Price Approval (WPA) under para 15 DPCO, 2013.**

6.1. The Authority discussed the matter and approved the guidelines for prosecuting companies launching new drugs Without Price Approval (WPA) under para 15 of DPCO, 2013.



**7. Agenda Item no. 7: Monitoring & Enforcement of Ceiling Price of Coronary Stent and Monitoring status of other medical devices.**

7.1 The Authority noted the contents relating to monitoring prices of Medical Devices. The Authority observed that in order to monitor the price movement of notified medical devices, a data-base of remaining 18 medical devices is required to be developed. In this context, the Authority noted that a meeting has been scheduled on 15<sup>th</sup> March, 2017 at NPPA with the representatives of major Medical Devices Associations to discuss the format of data-base. The Authority decided that the data base for medical devices should be in place within 45 days as far as possible.

**8. Additional discussions-**

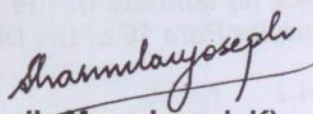
8.1 The Authority took a serious view about submission of incomplete data/information by certain companies while representing against draft calculation sheet and decided that such incomplete representations are to be rejected without any further correspondence with the companies. The Authority also directed that an OM be issued in this regard.

8.2 The Authority also asked NPPA office to ensure that ceiling price fixation of all the scheduled formulations where market data is available be completed by April 30, 2017. The Authority requested Chairman, NPPA to remind the Department of Pharmaceuticals (DoP) on the required amendment to fix the ceiling prices of those formulations, in respect of which market data is not available.

8.3 The Authority reviewed the status of compliance of review cases and directed that wherever the required information has been provided, the cases should be decided and informed to the Authority in the next meeting.

8.4 The Authority discussed the issue regarding increase of Wholesale Price Index (WPI) for the year 2016 over 2015 and decided that final figure may be obtained from the Department of Industrial Policy & Promotion (DIPP), Ministry of Commerce & Industry. The Authority accordingly decided that NPPA could issue an OM and consolidated notification in respect of ceiling prices of 678 formulations. In respect of coronary stents, a separate notification for revision of ceiling price based on WPI may also be issued as the ceiling prices of coronary stents were fixed and notified under para 19 of DPCO, 2013. The notifications thus issued could be placed before the next meeting of the Authority for information.

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

  
(Dr. Sharmila Mary Joseph K)  
Member Secretary