गोपनीय: Confidential

मिसिलस.- 8(44)/2017/डी.पी/एनपीपीए-डीवी-II

F. No. 8(44)/2017/DP/NPPA-Div. II

कार्यवाहीस. : 176/44/2017/F

Proceeding No : 176/44/2017/F

Minutes of the 176th and 44th meeting of Authority under DPCO, 2013 held on 26.4.2017 at 11.00 A.M.

I. 1. The 176th overall meeting of the Authority, which is the 44th under the DPCO, 2013 was held on 26th April, 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 Umesh Dongre, Adviser (Cost), Deptt. of Expenditure, 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)
(v) Shri A.P.S. Sawhney, Director (Overcharging)
(vi) Shri Baljit Singh, Asstt. Director (Pricing)
(vii) Shri Prasenjit Das, Asstt. Director (Pricing)
(viii) 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 43rd Meeting held on 29.3.2017.

1.1 The Authority confirmed the minutes of the overall 175th and the 43rd Meeting held on 29.3.2017 under DPCO, 2013.

2. Agenda Item no. 2: Action Taken Report

2.1 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 the following 16 formulations at the meeting. The Authority approved the ceiling prices in respect of following

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formulations (except 3 formulations viz. Snake venom antiserum- Lyophilized polyvalent Powder for Injection [2(a) or 2(b)], Heparin 5000 IU/ml Injection [4(a) or 4(b)] and IUD containing Copper- as licensed [8(a) or 8(b)]. The ceiling prices of these formulations would be notified after obtaining clarification from the Department of Pharmaceuticals (DoP) in the light of its recent OM F. No. 31026/31/2016-PI.I (Pt-III) dated 20.4.2017 when states thus "*Government clarifies that while fixing the ceiling prices of scheduled formulations, Moving Annual Turnover (MAT) value and PTR of only those medicines/formulations shall be considered which are having 1% or more market share*". The Authority noted that the ceiling price of these formulations can be notified after discussions with/clarification from DoP in this regard for computing 1% market share and based on the discussions/clarification, the ceiling prices will be notified separately [2(a) or 2(b), [4(a) or 4(b)] and [8(a) or 8(b)] in respect of these 3 (three) formulations).

S. NO.	UNIQUE NO. AS PER NLEM	NAME OF THE FORMULATION/ COMPOSITIONS	STRENGTH	Dosage Form	Unit for ceiling price	Proposed ceiling price under NLEM, 2015 (Rs.)
A. Common Formulations						
Section 4–Antidotes and other substances used in poisoning						
4.2–Specific						
1	4.2.11	Snake venom antiserum - Soluble/liquid polyvalent		Injection	10ML Pack	351.44
2(a)	***4.2.11***	***Snake venom antiserum- Lyophilized polyvalent***		***Powder for Injection***	***10ML Pack***	***527.21***
2(b)		***Based on DOP's OM dated 20.04.2017***				***534.29***
Section 10–Medicines affecting blood						
10.2–Medicines affecting coagulation						
3	10.2.2	Heparin	1000 IU/ml	Injection	PER ML	14.80
4(a)	***10.2.2***	***Heparin***	***5000 IU/ml***	***Injection***	***PER ML***	***36.73***
4(b)		***Based on DOP's OM dated 20.04.2017***				***39.57***
Section 12–Cardiovascular medicines						
12.1–Medicines used in angina						
5	12.1.4	Glyceryl trinitrate	5 mg/ml	Injection	Per ML	6.21
12.4–Medicines used in shock and heart failure						
6	12.4.1	Digoxin	0.25 mg/ml	Injection	Per ML	3.16
Section 21–Hormones, other endocrine medicines and contraceptives						
21.2.2–Intrauterine devices						
7	21.2.2.1	Hormone releasing IUD	Contains 52 mg of Levonorgestrel		1 IUD	3,509.95
8(a)	***21.2.2.2***	***IUD containing Copper***	***As licensed***		***1 IUD***	***260.87***
8(b)		***Based on DOP's OM dated 20.04.2017***				***283.82***
B. New Formulations						
Section 6–Anti infective medicines						
6.2.2–Other antibacterials						
9	6.2.2.9	Vancomycin	250 mg	Powder for Injection	Each Pack	201.20

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Section 8 –Antineoplastic/ immunosuppressives and medicines used in palliative care						
8.1–Antineoplastic medicines						
10	8.1.19	Etoposide	50 mg	Capsule	Per Capsule	51.44
Section 12–Cardiovascular medicines						
12.4–Medicines used in shock and heart failure						
11	12.4.4	Noradrenaline	2 mg/ml	Injection	Per ML	24.38
Section 19–Ear, nose and throat medicines						
12	19.1	Budesonide	100 mcg/dose	Nasal Spray	1 Dose	0.85
13	19.1	Budesonide	50 mcg/dose	Nasal Spray	1 Dose	0.96
Section 20–Gastrointestinal medicines						
20.3–Anti inflammatory medicines						
14	20.3.1	5-aminosalicylic acid	500 mg Retention Enema	Suppository	Per Suppository	15.99
C. Common Formulations (Explanation to Schedule-I) - NIL						
D. New Formulations (Explanation to Schedule-I)						
Section 12–Cardiovascular medicines						
12.1–Medicines used in angina						
15	12.1.5	Isosorbide-5-mononitrate	60 mg	SR Capsule	Per Capsule	3.29
16	12.1.5	Isosorbide-5-mononitrate	30 mg	SR Capsule	Per Capsule	3.32

4. Agenda Item no. 4: Review orders issued by DOP in respect of M/s Glenmrk Pharmaceuticals Ltd., M/s Bayer Zydus Pharma Pvt. Ltd., M/s Wockhardt Ltd. and M/s Alkem Lab. Ltd. for price fixation/revision.

4.1 Noted and approved.

5. Agenda Item no. 5: Form-I application submitted by M/s Aristo Lab. Pvt. Ltd. & M/s Aristo Pharmaceuticals Pvt. Ltd. for retail price approval of Monocef-SB 125mg injection under DPCO, 2013.

5.1 Noted and approved.

5(b) Agenda Item no. 5(b): Approved Form-I applications for retail price approval in 40th Authority meeting (held on 23.01.2017) and pending for notification under DPCO, 2013.

5.1 The Authority approved the notifications subject to 100% IPDMS compliance.

6. Agenda Item no. 6: Status of No data cases and Monopoly cases where retail channel data is not available.

6.1 Noted.

7. Agenda Item no. 7: Fixation of ceiling prices of Schedule-I formulations under DPCO, 2013 where retail channel data is not available.

7.1 Noted.

8. Agenda Item no. 8: Status of Review orders issued by DOP which are pending with NPPA for implementation.

8.1 Noted

9. Agenda Item no. 9: OMs issued by DoP on pricing and other related issues.

9.1 Noted. The Authority took note of the office memoranda issued by Department of Pharmaceuticals (DoP) on 20th April 2017. The Authority after detailed discussions decided that NPPA would issue clarificatory OMs:-

(i) The Authority took note of the OM regarding revision of ceiling price due to revision of WPI and in respect of formulations which have shifted to non-scheduled category due to amendment of Schedule – I of DPCO, 2013 and based on the discussions in DoP between Secretary, DoP and Chairman, NPPA & Member Secretary, NPPA in which Secretary, DoP specifically directed that the order is for prospective cases without any retrospective effect, it was decided to issue appropriate follow up O.M.

(ii) The Authority also took note of the OM regarding submission of detailed agreement between manufacturer and marketer and observed that NPPA was never asking for information on trade secrets or business plans of pharmaceutical companies. However, Authority decided to further clarify it through an O.M.

(iii) Regarding the OM of DoP on the issue of clubbing data of company-wise medicines or taking independent brand-wise data for determining 1% market share, the Authority decided to discuss the matter with DoP again, with empirical data on advised by Secretary, DoP.

(iv) In respect of DoP's OM regarding revision the ceiling prices, the Authority noted it.

10. Agenda Item no. 10: Minutes of the 4th meeting of Committee of Experts under para 11(3& 4) held on 19.4.2017 at 11:00 AM in NPPA.

10.1 Noted.

11. **Agenda Item no. 11: Guidelines for discontinuation of scheduled formulations**

11.1 The proposed modification in the guidelines for discontinuation related to Medical devices was approved by the Authority.

12. **Agenda Item no. 12: Form IV received from M/s India Medtronic Pvt. Ltd. and M/s Abbott Healthcare Ltd. on discontinuation of Coronary Stent (scheduled formulations) under para 21(2) of DPCO, 2013.**

12.1 The Authority discussed the matter in detail and directed that Form-IV applications made by both the companies may be rejected on the grounds as under:-

(a) M/s India Medtronic Pvt. Ltd. in its application sought immediate discontinuation of Resolute Onyx Zotarolimus Eluting Coronary stent System which was in contravention of para 21(2) of DPCO, 2013.

(b) The application of M/s Abbott Healthcare Ltd. was unsigned.

(c) Both the companies have to strictly follow DoP's instructions issued vide letter no. 31026/05/2017-Pricing dated 21.02.2017 and apply for withdrawal, if

required, within two weeks before the expiry of six months' period from the date of the DoP's letter.

(d) However, in case of adverse inputs regarding patient safety, application for withdrawal should specifically mention that reason.

(e) If the company needs special price for any special or innovative feature that it claims, separate application may be made for ceiling/retail price under para 11(3&4) and para 19 of DPCO, 2013.

13. Agenda Item no. 13: Compliance of IPDMS by pharmaceutical companies

13.1 The Authority took a serious note that many companies have not yet registered in IPDMS and- have not filed the requisite forms for their products despite several notices by the Government.

14. Agenda Item no. 14: Formulations launched by Pharmaceutical companies without taking retail price approval from NPPA as required under para 15(2).

14.1 The Authority took a serious note of the matter and observed that action may be initiated against errant companies, if any, for their having launched formulations without obtaining the required approval, in contravention to para 15(2) , read with paras 2(u) and 2(g) of DPCO 2013.

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

(Dr. Sharmila Mary Joseph K)
Member Secretary