

गोपनीय : Confidential

मिसिल स. 8(8)/2013 डी.पी./एन पी पी ए- डीवी-II

F. No. 8(8)/2013/DP/NPPA-Div. II

कार्यवाही स. : 140/8/2013/F

Proceeding No : 140/8/2013/F

Minutes of the 140<sup>th</sup> and 8<sup>th</sup> meeting of Authority under DPCO 2013 held on 1<sup>st</sup> November, 2013 at 12.00 Noon.

The 140<sup>th</sup> meeting of the Authority which is 8<sup>th</sup> under the DPCO 2013 was held on 1<sup>st</sup> November, 2013 at 12.00 Noon under the chairmanship of Shri C. P. Singh Chairman, NPPA. The following members of the NPPA were present:-

- (i) Shri Sanjay Kumar, Member Secretary, NPPA.
- (ii) Shri K.L. Prasad, Member (Ex-Officio), Adviser, Economic Division, Dept. of Economic Affairs.
- (iii) Shri L.M. Kaushal, Director (Cost) representing Adviser (Cost), Deptt. of Expenditure, Ministry of Finance
- (iii) Shri A.K. Pradhan, Deputy Drug Controller, representing the DCG(I), Department of Health.

The following officers also attended the meeting and assisted the Authority in its deliberations:-

- (i) Shri A.K. Gautam, Adviser (Cost)
- (ii) Shri A.K. Saha, Director (Overcharging)
- (iii) Shri Lalsanglur, Director (Admin. & Overcharging)
- (iv) Shri A.K. Khurana, Director (Pricing & Overcharging)
- (v) Shri S. K. Bhatt, Dy. Director (Technical)
- (vi) Smt Manmohan Kaur, Dy. Director (Cost)
- (vii) Shri Manish Goswami, Dy. Director (Cost)
- (viii) Shri T. R. Satish Chandran, Asstt. Director (Cost)
- (ix) Shri Suneel Chopra, Consultant (Legal)

#### **Agenda Item no. 1**

1.0 Members of the Authority who participated in the 139<sup>th</sup> and 7<sup>th</sup> Meeting under DPCO, 2013 confirmed the minutes of the meeting.

2 **Action Taken Report:**

2.0 Noted.

**Agenda Item no. 3:**

3.0 The Authority had detailed deliberations regarding the price fixation of scheduled formulations under DPCO, 2013 relating to 51 cases proposed in the Agenda and noted that the price fixation under the present proposal was made after re-verification of data from IMS Health and also the data furnished by the manufacturers. The Authority also recalled the observations during the 1<sup>st</sup> meeting and noted that NPPA is constrained to fix the ceiling price based on the available data at present. The data available on the internet is also inadequate. Moreover, the MAT value of different manufactures is also not available from the data available through internet search. Therefore, NPPA has taken a view that initially the prices may be worked out based on the IMS Health/and other best available data and later on the notified ceiling prices may be revisited in extra-ordinary circumstances and in public interest at large, if called for.

3.1 The Authority considered and approved the prices of 26 formulation packs for fixing/notifying the ceiling price under para 4 of DPCO, 2013 based on the data furnished by IMS Health and companies. In respect of case at Sr. no 24 of Annexure A relating to Hepatitis B vaccine Injection, it was informed to the Authority that NPPA has recently received revised data from IMS Health after the circulation of agenda. *under* *circumstances* Therefore, the working has been revised and circulated during the meeting. The Authority noted and approved the ceiling price of Rs. 101.09 as against the price of Rs. 111.00 as earlier proposed in the agenda. A Statement showing the prices approved and percentage of decrease from the highest price in the zone of consideration in respect of each medicine is enclosed as Annexure - A.

3.2 The Authority considered and approved the prices of 22 formulation packs for fixing/notifying the ceiling price under para 6 of DPCO, 2013 based on the Monopoly conditions i.e. where data in respect only one company is available. A Statement showing the prices approved in respect of each medicine is enclosed as Annexure - B.

3.3 The Authority considered the prices of the 3 formulation packs for fixing/ notifying the ceiling price under para 4 of DPCO, 2013 based on the representations of the company(ies) and clarification/revised data received from IMS Health. In respect of case at Sr. no. 1 of Annexure C regarding Oral Poliomyelitis vaccine (LA) solution, the Authority directed to put up a detailed note and re-look at the data ~~and~~ <sup>therefore</sup> ~~the~~ case was deferred. Thus, the Authority approved 2 cases and a Statement showing the prices approved and percentage of decrease from the highest price in the zone of consideration in respect of each medicine is enclosed as Annexure - C.

**Agenda Item no. 4:**

4.0 The retail price fixation of new formulation of M/s Mankind Pharma Ltd. for Glibenclamide & Metformin HCL (Extended release) tablet was discussed in detail. As per the workings based on IMS Health data, the price works out to be Rs. 2.68 per tablet i.e. Rs. 26.80 for 10's pack. <sup>Since the applicant has claimed a price</sup> The Authority approved a retail price of Rs. 25.66 for 10's pack, as claimed by the company as it is lower than the price worked <sup>of</sup> out by NPPA.

[ Rs 25.66 for each pack of 10 tablets ]

**Agenda Item no. 5:**

5.0 The retail price fixation of new formulation of M/s Torrent Pharmaceuticals Ltd. for Olmetor M 25mg tablet was discussed in detail. The Authority approved a retail price of Rs. 8.46 per tablet against the retail price of Rs. 8.50 per tablet as claimed by the company.

**Agenda Item no. 6:**

6.0 The retail price fixation of new formulation of M/s Torrent Pharmaceuticals Ltd. for Olmetor M 50mg tablet was discussed in detail. The Authority approved a retail price of Rs. 9.39 per tablet against the retail price of Rs. 9.90 per tablet as claimed by the company.

**Agenda Item no. 7:**

7.0 The retail price fixation of new formulation of M/s Torrent Pharmaceuticals Ltd. for Telday M50 tablet was discussed in detail. The Authority approved a retail price of Rs. 8.87 per tablet against the retail price of Rs 11.00 per tablet as claimed by the company.

**Agenda Item no. 8:**

8.0 The retail price fixation of new formulation of M/s Indoco Remedies Ltd. for Clamchek Forte D.S. suspension 30 ml was discussed in detail. The Authority approved a retail price of Rs. 2.85/ml against the retail price of Rs. 3.13/ml as claimed by the company.

**Agenda Item no. 9:**

9.0 Noted

**Agenda Item no. 10:**

10.0 Guideline in respect of Price Fixation of Non-Scheduled Formulations under Para 19 of the DPCO, 2013 was presented to the NPPA. The Authority discussed in detail in line with the provisions of para 19 & 20 of DPCO, 2013. It is deliberated that the margin of 35% proposed in the agenda <sup>was</sup> needs to be re-looked in line with the -16% margin allowed over the average PTR in respect of the Scheduled medicines under para 5 & 6. It is also deliberated that the legal stand taken by the NPPA in various court is different than the proposed guidelines. The Authority decided that the provisions of para 19 & 20 of DPCO, 2013 are very clear <sup>Hence there</sup> with regard to the <sup>no need for any further guideline</sup> prices of non-scheduled medicines may be regulated with the 10% price increase as laid down in the DPCO, 2013.

10.1 In view of the above, the Authority directed that these guidelines may not be required at this stage.

**Supplementary Agenda**

The Authority also discussed the supplementary agenda.

**Agenda Item no. 1:**

1.0 The Authority considered and approved the prices of one formulation pack for fixing/notifying the ceiling price under para 6 of DPCO, 2013 based on the Monopoly conditions i.e where data in respect only one company is available. A Statement showing the prices approved in respect of each medicine is enclosed as Annexure - D.

**Agenda Item no. 2:**

2.0 The retail price fixation of new formulation of M/s Macleods Pharmaceuticals Ltd. for Cefolac OZ tablet was discussed in detail. The Authority approved a retail price of Rs. 1.60 per tablet as claimed by the company.

**Agenda Item no. 3:**

3.0 The retail price fixation of new formulation of M/s Strides Ltd. for Voglibose 0.2mg & Metformin HCL 500mg (SR) tablet was discussed in detail. The Authority approved a retail price of Rs. 5.50 per tablet as claimed by the company.

**Agenda Item no. 4:**

4.0 The retail price fixation of new formulation of M/s Emcure Pharmaceuticals Ltd. for Filet S injection was discussed in detail. The Authority approved a retail price of Rs. 110.99 per injection against the retail price of Rs. 205.00 per Injection (inclusive of 5% VAT) as claimed by the company.

**Agenda Item no. 5:**

5.0 The retail price fixation of new formulation of M/s Strides Ltd. for Voglibose 0.3mg & Metformin HCL 500mg (SR) tablet was discussed in detail. The Authority approved a retail price of Rs. 5.80 per tablet as claimed by the company.

**Agenda Item no. 6:**

6.0 The retail price fixation of new formulation of M/s Macleods Pharmaceuticals Ltd. for Macfast Drops was discussed in detail. The Authority approved a retail price of Rs. 1.21/ml against the retail price of Rs 1.93/ml as claimed by the company.

**Agenda Item no. 7:**

7.0 The retail price fixation of new formulation of M/s Macleods Pharmaceuticals Ltd. for Cefolac Drops was discussed in detail. The Authority approved a retail price of Rs. 3.49/ml against the retail price of Rs 4.09/ml as claimed by the company.

**Agenda Item no. 8:**

8.0 Noted.

**Agenda Item no.9:**

8.0 In compliance with the review order of M/s Alembic Pharmaceuticals Ltd. under para 31 of DPCO, 2013 against the S.O.no. 1577(E) dated 14.06.2013 fixing ceiling price of Azithromycin 500mg tablet, the price of Rs. 20.51 per tablet was approved as against the earlier notified price of Rs. 19.86 per tablet.

(Sh. R.K. Paul)  
Member (Ex-Officio)

(Sh. G. N Singh)  
Member (Ex-Officio)

(Dr. K.L Prasad)  
Member (Ex-Officio)

(Shri Sanjay Kumar)  
Member Secretary

(Shri C.P. Singh) / 1/12/2013  
Chairman

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