गोपनीय : Confidential

मिसिल स.-8(3)/2013 डी.पी./एन पी पी ए- डीवी-II

F. No. 8(3)/2013/DP/NPPA-Div. II

कार्यवाही स. : 135/3/2013/F

Proceeding No: 135/3/2013/F

Minutes of the 135th and 3rd meeting of Authority under DPCO 2013 held on 28st June, 2013 at 12.30 P.M.

The 135th and 3rd meeting of Authority under DPCO 2013 was held on 28st June, 2013 at 12.30 P.M. under the chairmanship of Shri C. P. Singh Chairman, NPPA. The following members of the NPPA were present:-

- Shri Sanjay Kumar, Member Secretary, NPPA. (i)
- Dr. G. N. Singh, Drugs Controller General (India), Member (Ex-Officio), alongwith Shri A.K. Pradhan, Deputy Drug Controller, Department of Health. (ii)
- Shri K.L Prasad, Member (Ex-Officio), Adviser, Economic Division, Dept. of (iii) Economic Affairs.

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

- Shri A.K.Gautam, Advisor (Cost) (i)
- Shri A.K. Saha, Director (Overcharging)
- (ii) Shri S. K. Bhatt, Dy. Director (Technical)
- (iii) Shri Singh Veer Pratap, Dy. Director (Cost)
- (iv) Shri Manish Goswami, Dy. Director (Cost)
- (v) Shri. T.R. Satish Chandran, Asstt. Director (Cost)
- (vi) Shri S.S. Agarwal, Asstt. Director (Cost)
- (vii) Smt. Babita Singh, Asstt. Director (Cost) (viii)

Agenda Item no. 1

 Members of the Authority who participated in the 134th and 2nd Meeting under DPCO, 2013 confirmed the minutes of the 2nd meeting.

2. Action Taken Report: Noted

The Authority was informed that as per the decision taken in the last meeting held on 21.06.2013, price fixation orders have been issued in respect of 40 cases of scheduled formulations under DPCO 2013.

Agenda Item no. 3:

The Authority had detailed deliberations regarding the price fixation of scheduled formulations under DPCO, 2013 relating to 38 fresh cases proposed in the Agenda. The Authority was informed that in one case at Sr. No. 21 related to medicine Cytosine arabinoside 500mg/vial, the price was calculated for 1 ml but this price has to be worked out for 1 vial pack of 500mg/vial as this formulation is an injectable and is marketed in the powder form. Accordingly, the price of this pack has been re-worked as Rs. 515.53/vial. Under the circumstances the Authority approved the reworked price of Rs. 515.53/vial in respect of Cytosine arabinoside medicine. In other case at Sr. No. 26 of the agenda relating to price fixation of Tamoxifen Citrate which is proposed to Rs. 4.35 per tablet of 10mg, it was informed that the price worked out as above is not comparable with the price already approved for the higher strength of 20mg which was notified at Rs. 2.77 per tablet. The case was further analysed and it was found that the higher price for the lower strength of 10mg is due to higher Price to Retailer (PTR) of Rs. 15.31 per tablet of this drug sold by one of the major manufacturers. The Authority therefore, decided that though the price parity with the strength of the drug is not comparable but the proposed price of 4.35 per tablet of 10mg will bring down the price of major player by about 76%. Therefore, Authority decided to fix the price as proposed and directed that both the cases i.e.

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10mg and 20mg tablet may be further examined for any correction, should that be called for.

- 4. In case of Sr. No. 7 relating to formulation 'Phenytoin Sodium 50 mg tablet', it was informed to the Authority that the ceiling price of Rs. 0.77 per tablet of 50mg has already been notified vide notification S.O. no. 1570(E) dated 14.06.2013. Therefore, the Authority decided to close the case. The Authority approved the prices of all the remaining 35 formulation packs for fixing / notifying the ceiling price under para 4 of DPCO, 2013. The list of formulations alongwith ceiling price approved by the Authority is given at Annexure-A.
- 5. The Authority then took up the supplementary agenda regarding price fixation of 14 formulations under DPCO, 2013 which was circulated during the meeting for its consideration. The Authority discussed and approved the ceiling price in respect of 14 cases as proposed as per Annexure-B.
- 6. The Authority thereafter discussed a supplementary agenda number 2 relating to reduction in price worked out in respect of the cases where number of companies is less than 5. The Authority noted that no specific percentage of reduction has been defined under para 6 of DPCO, 2013. Therefore, the Authority directed that all cases where there is definite reduction in price may continue to be processed and put up in the agenda for discussion and decision in this regard.
- 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 & B as mentioned above.

This issues with the approval of Chairman, NPPA.

(Sanjay Kumar) Member Secretary