गोपनीय : Confidential

मिसिल स.- 8(6)/2013 डी.पी./एन पी पी ए- डीवी-II

F. No. 8(6)/2013/DP/NPPA-Div. II

कार्यवाही स. : 138/6/2013/F

Proceeding No : 138/6/2013/F

Minutes of the 138th and 6th meeting of Authority under DPCO 2013 held on 19th August, 2013 at 12.00 Noon.

The 138th meeting of the Authority which is 6th under the DPCO 2013 was held on 19th August, 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) Smt. Aruna Sethi, Member (Ex-Officio), Adviser, Office of Chief Adviser Cost, Deptt. of Expenditure
- (iii) Shri S. Basu, Asstt. 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 R. Asokan, Director (Pricing)
- (ii) Shri A.K. Saha, Director (Overcharging)
- (iii) Shri Lalsanglur, Director
- (iv) Shri Jagdish Kumar, Director (M&S)
- (v) Shri S. K. Bhatt, Dy. Director (Technical)
- (vi) Shri Singh Veer Pratap, Dy. Director (Cost)
- (vii) Smt Manmohan Kaur, Dy. Director (Cost)
- (viii) Shri Manish Goswami, Dy. Director (Cost)
- (ix) Shri S.S. Agarwal, Asstt. Director (Cost)
- (x) Smt. Babita Singh, Asstt. Director (Cost)
- (xi) Shri T. R. Satish Chandran, Asstt. Director (Cost)
- (xii) Shri Sunil Chopra, Legal (Consultant)

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Agenda Item no. 1

- 1.0 Members of the Authority who participated in the 137th and 5th Meeting under DPCO, 2013 confirmed the minutes of the meeting.
- 1.1 The Authority observed that the agenda items were circulated to members giving little time to examine the agenda in detail. Keeping the above in view, the Authority directed that the agenda note should be circulated to all the members well in advance.
- 2 Action Taken Report:
- 2.0 Noted.

Agenda Item no. 3:

The Authority had detailed deliberations regarding the price fixation of scheduled formulations under DPCO, 2013 relating to 10 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 1st 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 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. Therefore, the Authority considered each case and approved the prices of all the 10 formulation packs for fixing / notifying the ceiling price under para 4 of DPCO, 2013. 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.

Agenda Item no. 4:

4.0 Ceiling price fixation of new formulation namely Millixim – O 100 DT tablets containing Cefixime Trihydrate eq. to Anhydrous Cefixime – 100 mg and Ofloxacin –

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100 mg manufactured by M/s Glenmark Pharmaceuticals Ltd. was discussed in detail. After a detailed discussion on the subject and also duly considering the provisions contained under para 5 of DPCO, 2013 with regard to calculation of retail price of "new drug" for existing manufacturers of scheduled formulations, the Authority approved ceiling price of Rs. 5.73 per tablet across the board. Since, M/s Glenmark was seeking a retail price of Rs. 5.50 per tablet, which is lower than the ceiling price worked out as per para 4 of DPCO, 2013, the Authority approved a retail price of Rs. 5.50 in respect of formulation namely Millixim — O 100 DT tablets containing Cefixime Trihydrate eq. to Anhydrous Cefixime — 100 mg and Ofloxacin — 100 mg manufactured by M/s Glenmark Pharmaceuticals Ltd.

Agenda Item no. 5:

5.0 Approved.

Agenda Item no. 6:

6.0 The agenda note stands withdrawn.

Agenda Item no. 7:

7.0 The agenda note stands withdrawn.

Agenda Item no. 8:

8.0 The Authority noted that para 10 (1) of DPCO, 2013 states that the notified prices prior to 31 May, 2012 shall remain in force upto 31 May, 2013 and the manufacturers may revise the prices of such scheduled formulations as per the annual wholesale price index from the previous calendar year announced by Department of Industrial Policy and Promotion and thereafter the formula as in paragraph 4(1) of this order shall be applied for fixing the ceiling prices of such formulations. It was also noted that para 16 (1) of DPCO states that the Government shall revise the ceiling prices of scheduled formulations as per the annual wholesale price index (WPI) for preceding calendar year on or before 1st April of every year and notify the same on the 1st day of April every year.

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- 8.1 Since, para 10 and 16 of DPCO, 2013 indicate two different dates for revising the ceiling prices based on the WPI, the Authority directed to seek clarifications in this regard from the Department of Pharmaceuticals with regard to the effective date of price revision to be considered based on the WPI. In view of the above, the Authority felt that the agenda item can be taken-up for consideration only after obtaining clarification from the DOP on the subject.
- This issues with the approval of Chairman, NPPA.

(Sanjay Kumar) Member Secretary
