F. No. 19(719)/2016/DP/NPPA/Div.II

National Pharmaceutical Pricing Authority

Subject: Minutes of the 6th meeting of Committee of Experts under para 11(3& 4) held on 13.10.2017 at 03:00 PM in NPPA

5th meeting of the "Committee of Experts" was held on 13.10.2017 under the Chairmanship of the Sh. Kalyan Nag, Adviser (Cost), in the Conference Room of NPPA. The Chairman extended warm welcome to the members who participated. The quorum was present to conduct the meeting. The following members/officers attended the meeting:-

1. Prof. Y. K. Gupta, Prof. & Head, Deptt of Pharmacology, AIIMS.
2. Dr. V. K. Bahl, Head, Deptt of Cardiology, AIIMS
3. Dr. Naval K. Vikram, Professor, Deptt of Medicine, AIIMS
4. Prof. D P Pathak, Director, DIPSAR
5. Dr. Rajni Kaul, Scientist-G, ICMR
6. Sh. P. K. Abdul Kareem, Addl. Economic Advisor, Deptt of Economic Affiars, MoF
7. Sh Chandrasekhar Ranga, Dy. Drug Controller, DCGI
8. Dr. Ritu Mathur, Additional Director, CGHS MSD
9. Sh. Rakesh Pandey, Dy. Director, O/o the CAC, Deptt of Expenditure, MoF
10. Sh. A P S Sawhney, Director (Pricing), Convenor.
11. Sh. Baljit Singh, Assistant Director (Pricing), NPPA
12. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA.

At the outset, the members of the Committee were apprised about the para 11(3&4) of DPCO, 2013. The item-wise deliberation and decision are minuted as under:

1(i) Agenda No.1 Application under para 32(iii) of DPCO, 2013 relating to Paclitaxil lipid suspension for injection 30 mg and 60 mg made by M/s Intas Pharmaceuticals Ltd

The Committee observed that the company did not submit the requisite information. Accordingly, the Committee opined that a last reminder letter may be issued to the company directing to furnish the requiste documents. If the same is not received within 20 days from the date of issue of letter, the matter would be treated as closed.

1 (ii)Agenda No. 2. Representation prior to Notification in respect of Surfactant Suspension for intratracheal instillation (as licenced)

The Committee observed that different surfactants available in the market have highly variable contents of Phospholipids per ml. From the information placed on the table, it varies from 10.8 mg/ml to 80 mg/ml and the dosage varies from 1.25ml/kg to 7ml/kg. The Committee also observed that there are other components in the surfactants but are of less consequence. Therefore, the Committee recommended that the price may be considered for fixation based on major component i.e. Phospholipids and in miligram(mg) as units.

1 (iii) Agenda No. 3. Review Order No. 31015/102/2016-PI.I dated 24.08.2017 in respect of M/s Sun Pharma Laboratories Ltd-Propranolol 40 mg capsules

The Committee deliberated the issue in details and observed that ceiling price of Propranalol 40 mg capsules has been worked out based only TR variants of capsule having 1% or more market share. Further, the Committee is of the considered view that there is no substantial therapeutic advantage in the TR variants from the normal capsules. In view of the above, the Committee recommended that the product of Sun Pharma Laboratories Ltd i.e.BETACAP 40MG CAPSULE TR 10 should not be excluded in the ceiling price fixation of Propranolol 40 mg capsule.

1(iv) Agenda No. 4 Review Order No. 31015/13/2017-Pricing dated 24.08.2017 in respect of M/s Sun Pharma Laboratories Ltd-Methylprednisolone Injection 40mg/ml

The Committee deliberated the issue in details and opined that lyophilisation of a product is a minor incremental innovation which does not have any significant therapeutic advantage which justifies separate pricing. Hence, the Committee recommended that lyophilised version of methylprednisolone injection 40mg/ml including IVEPRED 40MG Injection 1 ml is a scheduled drug as per DPCO, 2013.

1 (v) Agenda No. 4 Representation of M/s Biological E. Ltd in respect of Japanese encephalitis Vaccine

The Committee deliberated the issue in details and opined that the dose of Japanese encephalitis vaccine is 2.5-3 mcg for children less than 3(three) years and 5-6 mcg for children above 3(three) years. Accordingly, the Committee recommended that the ceiling price of Japanese encephalitis may be fixed in two separate groups by taking vaccine containing dosage of 2.5-3 mcg as one group and dosage containing 5-6 mcg as another group.

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

(A. P. S. Sawhney)
Director (Pricing)

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All member of the Committee of Experts