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

National Pharmaceutical Pricing Authority

Subject: Minutes of the 4th meeting of Committee of Experts under para 11(3&4) held on 30.01.2017 at 11:00 AM in NPPA

A meeting of the "Committee of Experts" was held on 30.01.2017 under the Chairpersonship of the Sh. Kalyan Nag, Adviser (Cost), in the Conference Room of NPPA. The Chairperson extended warm welcome to the members who participated, especially Sh. Rakesh Pandey, Dy. Director, O/o Chief Adviser Cost, Deptt of Expenditure, MoF who has been co-opted as member. Sh. P. K. Abdul Kareem, Addl. Economic Adviser, Deptt of Economic Affairs, MoF has also been co-opted. The quorum was present to conduct the meeting. The following members/officers attended the meeting:-

(i) Dr. Y. K. Gupta, Prof. & Head, Deptt of Pharmacology, AIIMS –Member.
(ii) Dr. Naval K Vikram, Prof., Deptt of Medicine, AIIMS, New Delhi–Member.
(iii) Sh. Chandrasheka Ranga, Dy. DC (I), O/o the DCGI–Member.
(iv) Sh. Vijay Kumar, Scientist 'G', ICMR, New Delhi –Member.
(v) Sh. Rakesh Pandey, Dy. Director, O/o the CAC, Deptt of Expenditure, MoF – Member.
(vi) Sh. A.K.Khurana, Director (Pricing), Convenor.
(vii) Sh. Baljit Singh, Assistant Director (Pricing), NPPA.
(viii) Sh. Prasenjit Das, Assistant Director (Pricing), NPPA.

2. At the outset, the members of the committee were apprised about the provisions of para 11(3&4) of DPCO, 2013. Thereafter, the Committee took up the agenda circulated for its consideration. The item-wise deliberation and decision are minuted as under:-

I. Consideration of Review Orders issued by DoP for examination on merit under para 11 (3&4) of DPCO, 2013

a. Budesonide Inhalation 100mcg/dose, Budesonide Inhalation 200mcg/dose, Budesonide + Formeterol Inhalation (Budesonide 200mcg+ Formeterol 6 mcg/dose), Budesonide + Formeterol Inhalation (Budesonide 400mcg+ Formeterol 6 mcg/dose), Budesonide + Formeterol Inhalation (Budesonide 100mcg+ Formeterol 6 mcg/dose) (Review Order No: 31015/27/2016-PI.I dated 14.9.2016).

b. Digihaler FR 100/200/400 and Budesonide/ Formeterol (100/6, 200/6 and 400/6)- Consideration of representation made by company under DPCO, 2013.

The Committee observed that there are different inhalations based on drug delivery devices. This includes conventional and innovative delivery devices. Conventional delivery devices requires manual pressing and has to be co-ordinated with the inspiration stage by the patients. Thus, it requires certain training/explanation by the physicians. Innovative delivery devices/Inhalar with dosage counter uses the similar mechanism but additionally have a dose counter (manual/digital) which gives simultaneously information about remaining doses of the available drug in Inhaler. Digital dose counter are more accurate than manual dose counter, as the manual dose counter gives only the range of remaining doses of available drug in the device. There is no clinical data/survey report/study available to indicate that additional features improve clinical efficiency. Another category i.e. Autohaler releases drugs on inspiration and this technique is based on the negative pressure created by inspiration & claimed to have advantages of no need of synchronization of breathing, as required under conventional devices (with/without dose counter). Though this device seems to be technically superior, however, there is also no clinical data/survey report/study available showing significant benefit in terms of therapeutic outcome with this additional feature.

Though all the above additional features are meant to improve the compliance, its clinical data is important to establish its efficiency. The Committee desired to seek the clinical data/survey report/study from the company concerned to substantiate their claim of separate pricing for different devices. Till such time, all the devices will be treated at par.

c. Erythropoietin 2000IU and 10000IU Injection (Review Order No: 31015/20/2016-PI.I dated 04.07.2016)

The Committee observed that in respect of the subject formulation, the prefilled syringe is a modification which will ease the drug administration and have no significant therapeutic outcome and clinical advantage. It cannot be considered as significant therapeutic innovation. Hence, the request for price revision under para 11(3&4) of DPCO, 2013 may not be considered.

II. Consideration of representations made by companies on draft working sheets under para 11(3&4) of DPCO, 2013.

a. Hydroxypropyl Methylcellulose 2% Injection

The Committee observed that in respect of the subject formulation, the prefilled syringe is a modification which will ease the drug administration and have no significant therapeutic outcome and clinical advantage. It cannot be considered as significant therapeutic innovation. Hence, the request for price revision under para 11(3&4) of DPCO, 2013 may not be considered.

b. Metoclopramide 5mg/ml Injection

The Committee observed that in respect of the subject formulation, since it has single and multi dose usage, the request for separate price based on pack size under para 11(3&4) of DPCO, 2013 may be considered.

c. Tramadol 50mg/ml Injection

The Committee observed that in respect of the subject formulation, since it has single and multi dose usage, the request for separate price based on pack size under para 11(3&4) of DPCO, 2013 may be considered. The pack size of 1 ml and 2 ml may be treated as single use and the 20ml pack may be treated as multi use.

d. Small Volume Parenterals (SVP)

Since the issue relates to pack size wise price fixation of Gentamicin Injection 40mg/ml (in pack sizes of 2ml, 10ml, 20ml and 30ml); Dexamethasone Injection 4mg/ml (in pack size of 2ml, 10ml, 20ml and 30ml), Tetanus Toxoid Injection (in pack sizes of 5ml and 0.5ml) and Paracetamol Injection (in different pack sizes) was raised by IDMA as well as ASSOCHAM, however, the pack size wise ceiling price has been fixed in all the cases. It was informed to the Committee and thus, there no further discussions were made on the issue.

e. Dicyclomine 10mg/ml Injection

It was informed to the Committee that the issue is under review by the Deptt of Pharmaceuticals, thus, the issue may be deferred till the outcome of the review order.

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

(A.K.Khurana)
Director (Pricing)

Copy to:

All members of the Standing Committee