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

भारत सरकार

Government of India

रसायन और उर्वरक मंत्रालय

Ministry of Chemicals & Fertilizers

औषध विभाग

Department of Pharmaceuticals

राष्ट्रीय औषध मूल्य निर्धारण प्राधिकरण

National Pharmaceutical Pricing Authority

तीसरी/पांचवी मंजिल 5th / 3rd Floor,
वाई.एम.सी.ए. सांस्कृतिक केन्द्र बिल्डिंग
YMCA Cultural Center Building,
1, जय सिंह रोड़, नई दिल्ली-110001
1, Jai Singh Road, N. Delhi – 110001.

दिनांक :- **12.01.2017**

OFFICE MEMORANDUM

The undersigned is directed to forward herewith the Minutes of Meeting of 3rd Meeting of Committee of Experts (held on 28.12.2016) under para 11(3 & 4) of Drugs (Prices Control) Order, 2013.

(A. K. Khurana)
Director (Pricing)

1. Prof. Y. K. Gupta, Head, Department of Pharmacology, AIIMS, New Delhi.
2. Shri D. P. Pathak, Director, Delhi Institute of Pharmaceutical Science and Research (DIPSAR).
3. Dr. Sarita Dhawan, Add. Director, CGHS, New Delhi.
4. Sh. Somnath Basu, Asstt. Drug Controller, CDSC, O/o DCG(I).

Copy for information to:

1. PPS to Chairman, NPPA
2. PPS to MS, NPPA
3. PPS to Adviser(Cost), NPPA

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

National Pharmaceutical Pricing Authority

Subject: Minutes of the 3rd meeting of Committee of Experts under para 11(3& 4) held on 28.12.2016 at 11:00 AM in NPPA

A meeting of the "Committee of Experts" was held on 28.12.2016 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, Head, Deptt of Pharmacology, AIIMS.
2. Sh. D. P. Pathak, Director, DIPSAR.
3. Dr. Sarita Dhawan, Additional Director, CGHS.
4. Sh. Somnath Basu, Asstt Drug Controller, CDSCO, O/o DCGI.
5. Sh. A.K.Khurana, Director (Pricing), Convenor.
6. Sh. Baljit Singh, Assistant Director (Pricing), NPPA.
7. 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. 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. Carboplatin 10mg/ml Injection (Review Order No: 31015/33/2016-PI.I dated 19.9.2016)

The Committee observed that in respect of the subject formulation, the dosage is dependent on the body surface area & on the tolerability of the patient. The pack containing 150mg, 300mg, 450mg and 600mg is mostly used as a single dose depending on the requirement/ situation. Hence, the request for price revision under para 11(3&4) of DPCO, 2013 may not be considered.

b. Cisplatin 1mg/ml Injection (Review Order No: 31015/33/2016-PI.I dated 19.9.2016)

The Committee observed that in respect of the subject formulation, the dosage is dependent on the body surface area & on the tolerability of the patient. Thus, the packs are mostly used as a single dose depending on the requirement/ situation. Hence, the request for price revision under para 11(3&4) of DPCO, 2013 may not be considered.

c. Paclitaxel 30mg/5ml Injection (Review Order No: 31015/33/2016-PI.I dated 19.9.2016)

In respect of the subject formulation, the Committee observed that the separate pricing under para 11(3&4) of DPCO, 2013 may not be considered since it is used as a single dose depending upon the situation. The Committee considered the issue of polymer based nano particle paclitaxel and decided to seek evidence of therapeutic rational of the drug for consideration of a separate price in its next meeting.

d. **Carboxymethylcellulose 0.5% drops (Review Order No: 31015/25/2016-PI.I dated 30.8.2016)**

The Committee observed in respect of the subject formulation that it is commonly used in dry eye condition and it is required several times and have multiple usage/administration. The commonly used preservative has been permitted after due safety assessment. Most of the products have multi usage/dose. Single dose does not offer substantial advantage in terms of cost-benefit and compliance and no supporting authenticated evidences/ documents have been submitted. Hence, the request for price revision under para 11(3&4) of DPCO, 2013 may not be considered.

Further, the committee also opined that the letter may be written to the DCGI to analyse the toxic effects of Benzalkonium chloride(BAC) as preservative.

e. **Flucanozole 200mg/100ml Injection (Review Order No: 31015/14/2016-PI.I dated 07.9.2016)**

The Committee observed that in respect of the subject formulation, separate pricing due to usage of different packaging does not offer significant therapeutic and clinical advantage. Hence, the request for price revision under para 11(3&4) of DPCO, 2013 may not be considered.

f. **Gemcitabine 1gm Powder for Injection (Review Order No: 31015/12/2016-PI.I dated 04.8.2016)**

The Committee observed that in respect of the subject formulation, the representation is primarily commercial; not technical based and has no additional therapeutic advantage. Hence, the request for price revision under para 11(3&4) of DPCO, 2013 may not be considered.

g. **Filgrastim 300mcg Injection (Review Order No: 31015/12/2016-PI.I dated 04.8.2016)**

The Committee observed that in respect of the subject formulation, the prefilled syringe is a minor modification which will ease the drug administration and have no significant 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.

h. i. **Budesonide Inhalation 100mcg/ dose ii. Budesonide Inhalation 200mcg/dose iii. Budesonide+ Formeterol Inhalation (Budesonide 200mcg+Formeterol 6mcg/ dose) iv. Budesonide+ Formeterol Inhalation (Budesonide 400mcg+Formeterol 6mcg/ dose) v. Budesonide+ Formeterol Inhalation (Budesonide 100mcg+Formeterol 6mcg/ dose) (Review Order No: 31015/27/2016-PI.I dated 14.09.2016)**

The Committee decided to defer this agenda for the discussion in the next meeting.

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

a. Dexamethasone 4mg/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.

b. Gentamicin 40mg/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. Tetanus Toxoid 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.

d. Water for 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.

e. Hydroxypropyl Methylcellulose 2% Injection

The Committee decided to defer this agenda for the discussion in the next meeting.

f. Dicyclomine 10mg/ml Injection

The Committee decided to defer this agenda for the discussion in the next meeting.

g. Metoclopramide 5mg/ml Injection

The Committee decided to defer this agenda for the discussion in the next meeting.

h. Tramadol 50mg/ml Injection

The Committee decided to defer this agenda for the discussion in the next meeting.

i. **Paracetamol Injection/Infusion 150mg/ml of (i) 0.5 ml (Amp/ Vial) 75 mg/pack (ii) 1 ml (Amp/ Vial) 150 mg/pack (iii) 2 ml 300 mg/pack (iv) 3 ml 450 mg/pack (v) 15 ml 2250mg/pack (vi) 50 ml 7500mg/pack (viii) 100 ml 15000 mg/pack.**

   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.

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

(A.K.Khurana)
Director (Pricing)

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All members of the Standing Committee