

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

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,

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YMCA Cultural Center Building,

1, जय सिंह रोड, नई दिल्ली-110001

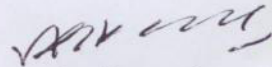
1, Jai Singh Road, N. Delhi - 110001.

दिनांक :- 26.4.2017

OFFICE MEMORANDUM

Subject: 4th meeting of the Committee of Experts under para 11(3&4) of DPCO, 2013.

The undersigned is directed to enclose the minutes of 4th meeting of the Committee of Experts under para 11(3 & 4) of DPCO, 2013 held on 19.4.2017. This is for your information and necessary action please.


(ए. के. खुराना)
निदेशक

Encl: As above.

To,

1. Prof. Y. K. Gupta, Prof. & Head, Deptt. of Pharmacology, AIIMS.
2. Sh. R. Chandrashekhar, Dy. Drug Controller, O/o the DCGI
3. Sh. P. K. Abdul Kareem, Addl. Economic Advisor, Deptt of Economic Affiars, M/o Finance.
4. Sh. Rakesh Pandey, Dy. Director, O/o the CAC, Deptt of Expenditure, M/o Finance.
5. Mohammad Ameel, Consultant, National Health Systems Resource Centre (NHSRC), M/o H&FW.

Copy to:

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

National Pharmaceutical Pricing Authority

Subject: Minutes of the 4th meeting of Committee of Experts under para 11(3& 4) held on 19.4.2017 at 11:00 AM in NPPA

A meeting of the "Committee of Experts" was held on 19.4.2017 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. Sh. R. Chandrashekhar, Dy. Drug Controller, O/o the DCGI
3. Sh. P. K. Abdul Kareem, Addl. Economic Advisor, Deptt of Economic Affairs, M/o Finance.
4. Sh. Rakesh Pandey, Dy. Director, O/o the CAC, Deptt of Expenditure, M/o Finance.
5. Mohammad Ameer, Consultant, National Health Systems Resource Centre (NHSRC), M/o H&FW.
6. Sh. A. K. Khurana, Director (Pricing), Convenor.
7. Sh. Baljit Singh, Assistant Director (Pricing), NPPA.
8. 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. Mohammad Ameer, Consultant, NHSRC informed that the division of Healthcare Technology, NHSRC is expertise in medical devices and not in drugs, hence inputs on items like cardiac stents and other medical devices can be only given. 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. Ondansteron 2mg/ml Injection (Review Order No: 31015/75/2016-PI.I dated 22.12.2016)

The Committee observed that Ondansteron 2mg/ml injection is an effective drug used primarily for nausea/vomiting, where other drugs used in anaesthesia are less effective. The parental dose in this situation varies upto 32 mg. In other indications, the dose is somewhat lower i.e. 4 mg. Thus, 10 ml vial may not always be used as multi-dose and it is used as single dose also. Hence, the request for price revision under para 11(3&4) of DPCO, 2013 based on the separate pricing of dispensing packs of 10ml vial may not be considered.

b. Pheniramine 22.75mg/ml Injection (Review Order No: 31015/100/2016-PI.I dated 10.3.2017)

The Committee observed that Pheniramine 22.75 mg/ml is an anti-allergy drug. The primary indication is any allergic condition. The conventional parental dose is around 25 mg to 50 mg. The single dose is, therefore, 2ml. In this case, 10ml pack may be considered as multi-dose and hence, the request for price revision under para 11(3&4) of DPCO, 2013 based on single and multi dose may be considered.

c. Dicyclomine 10mg/ml injection (Review Order No: 31015/99/2016-PI.I dated 05.4.2017)

The Committee observed that the unit dose of Dicyclomine 10mg/ml is of 1-2ml. More than this can be used as multi-dose. Hence, the request for price revision under para 11(3&4) of DPCO, 2013 based on single and multi-dose may be considered.

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

The Committee examined the documents/information submitted by the company and directed to sought the following additional information from the company:

- i) Copy of Phase III clinical trial report and PSUR data,
- ii) The evidence of superiority of the product in terms of efficacy over its normal version and the side effects, if any, and
- iii) Stability data in this regard.

With respect to the 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 nano formulation of Paclitaxil is being used for several years and at this stage can not be considered as novel formulation. Further, the committee also observed that there is some discrepancy in the nomenclature as stated by the company and in the licence granted by the DCG(I). The Committee directed to sought the following information from the company:

- i) Copy of clinical trial reports,
- ii) The evidence of superiority of the product in terms of efficacy over its normal version and the side effects, if any, and
- iii) Stability data in this regard.

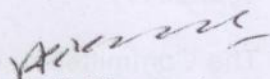
e. Budesonide Inhalation 100mcg/dose, Budesonide Inhalation 200mcg/dose, Budesonide + Formeterol Inhalation (Budesonide 200mcg+ Formeterol 6 mcg/dose), Budesonide + Formeterol Inhalation (Budesonide 400mcg+ Formeterol 6 mcg/dose), Budesonide + Formeterol Inhalation (Budesonide 100mcg+ Formeterol 6 mcg/dose)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

Due to paucity of time, the committee decided to defer to discuss on the issue till the next meeting.

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

Due to paucity of time, the committee decided to defer to discuss on the issues till the next meeting.

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


(A.K. Khurana)

Director (Pricing)

Copy to:

All members of the Committee of Experts.