By Special Messenger
Speed Post

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,
वाई.एम.सी.ए. सांस्कृतिक केन्द्र बिल्डिंग
YMCA Cultural Center Building,
1, जय सिंह रोड, नई दिल्ली-110001
1, Jai Singh Road, N. Delhi – 110001.
दिनांक :- 08.5.2017

OFFICE MEMORANDUM

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

The undersigned is directed to enclose the minutes of 4th (continued) meeting of the Committee of Experts under para 11(3 & 4) of DPCO, 2013 held on 02.5.2017. 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. Prof. Rakesh Yadav, Deptt of Cardiology, AIIMS.
3. Prof. Naval. K. Vikram, Deptt of Medicine, AIIMS.
4. Sh. P. K. Abdul Kareem, Addl. Economic Advisor, Deptt of Economic Affiars, MoF.
5. Ms. Rajni Kaul, Scientist-G, ICMR.
6. Prof. Sharad Wakode, DIPSAR.
7. Sh. Rakesh Pandey, Dy. Director, O/o the CAC, Deptt of Expenditure, MoF.
8. Dr. Ravi Kant Sharma, ADC, Office of the DCGI.

Copy 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 4th (continued) meeting of Committee of Experts under para 11(3& 4) held on 02.5.2017 at 10:00 AM in NPPA

4th meeting of the "Committee of Experts" was continued on 02.5.2017 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. Prof. Rakesh Yadav, Deptt of Cardiology, AIIMS
3. Prof. Naval. K. Vikram, Deptt of Medicine, AIIMS
4. Sh. P. K. Abdul Kareem, Addl. Economic Advisor, Deptt of Economic Affiars, MoF
5. Ms. Rajni Kaul, Scientist-G, ICMR
6. Prof. Sharad Wakode, DIPSAR
7. Sh. Rakesh Pandey, Dy. Director, O/o the CAC, Deptt of Expenditure, MoF
8. Dr. Ravi Kant Sharma, ADC, Office of the DCGI
9. Sh. A.K. Khurana, Director (Pricing), Convenor.
10. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA.

At the outset, the members of the committee were apprised about para 11(3&4) of DPCO, 2013. Thereafter, the Committee took up the remaining agenda (which could not be completed on 19.4.2017) 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. Paclitaxil Injection 30mg/5 ml (Review Order No: 31015/33/2016-PI.I dated 19.9.2016)

Since the company is yet to submit the requisite information as directed by the Committee, the Committee decided to defer the case till the receipt of requisite information.

b. 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)

The Committee observed that Budesonide is a respiratory medicine. The conventional dosage is 100mcg, 200mcg & 400mcg. This is often given in combination with Formeterol in dose of 6 mcg. There are different delivery systems available for inhalations ranging from simple/conventional inhalation device to metered dose inhaler/digital inhaler and autohaler. There may be other different variants/drug dispensing mechanisms available in the market. Although they offer technological advantage/ease of administration say in old age/children or patients with poor coordination ability, there is no significant difference in clinical efficacy and therapeutic outcome once an adequate dose is administered/delivered. Hence, separate

price for metered dose counter/digital inhaler and autohaler may not be considered, rather they should be clubbed together for the purpose of price fixation.

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

a. **DPT Vaccine**

The Committee observed that in most of the cases, single dose of 0.5ml is used and on a few occasions, multiple doses are used. The 5ml pack is less commonly used and 25ml is rarely used. The vaccine is also used in the immunization programmes. Hence, it is logical to put them all under one basket, thus, separate pricing for various packs of vaccines may not be considered.

b. **DPT+HIV+Hep B Vaccine**

The Committee observed that in most of the cases, single dose of 0.5ml is used and on a few occasions, multiple doses are used. The 2.5ml pack is less commonly used. The vaccine is also used in the immunization programmes. Moreover, the issue of prefilled syringe (PFS) was also discussed; PFS 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, it is logical to put them all under one basket, thus, separate pricing for various packs of vaccines may not be considered.

c. **Hepatitis B Vaccine**

The Committee observed that in most of the cases, single dose is used and on a few occasions, multiple doses are used. The vaccine is also used in the immunization programmes. Hence, it is logical to put them all under one basket, thus, separate pricing for various packs of vaccines may not be considered.

d. **Glucose 10% Injection**

The Committee recommended separate ceiling price fixation based on pack size as done in other IV Fluid cases.

e. Digihaler FB 100/200/400 and Budesonide/ Formeterol 100/6 mcg, 200/6 mcg, 400/6 mcg

The Committee observed that Budesonide is a respiratory medicine. The conventional dosage is 100mcg, 200mcg & 400mcg. This is often given in combination with Formeterol in dose of 6 mcg. There are different delivery systems available for inhalations ranging from simple/conventional inhalation device to metered dose inhaler/digital inhaler and autohaler. There may be other different variants/drug dispensing mechanisms available in the market. Although they offer technological advantage/ease of administration say in old age/children or patients with poor coordination ability, however, there is no significant difference in clinical efficacy and therapeutic outcome once an adequate dose is administered/delivered. Hence, separate price for metered dose counter/digital inhaler and autohaler may not be considered, rather they should be clubbed together.

f. Ceiling price consideration of MDI/DPI inhaler

The Committee observed that the inhalational drugs used for bronchial asthma are given by different methods like MDI, DPI, Soft-mist inhaler and Nebulizer. The DPI can be given as single dose, multi-dose and powder assisted system. This has advantage of portability, does not require much coordination and no spacer is required whereas MDI requires Aerosol which is also portable and independent, reproducing doses & has relatively low cost. In India, the Physician's feedback is that DPI is relatively less used as compared to MDI. Thus, there is not much significant clinical advantage in terms of therapeutic outcome by using DPI over MDI. The Committee, therefore, recommends that MDI & DPI to be merged together for ceiling price fixation as far as pricing is concerned and no separate price may be fixed for MDI and DPI.

g. Paclitaxil Lipid Suspension for injection 30 mg and 60 mg

Since the company is yet to submit the requisite information as directed by the Committee, the Committee decided to defer the case till the receipt of requisite information.

h. Stents-Synergy Evrolimus Eluting Platinum Chromium Coronary Stent with Bio-Absorbable polymer Systems (Boston Scientific).

The issue of Stents was discussed in detail. The company made the presentation before the Committee. The Committee observed that there has been technological advancement which the company claimed has resulted in less incidence of stent thrombosis and more procedure success as compared to their/other newer available stents. To conclusively say that there is a significant difference in terms of adverse impacts as compared to their/other newer currently available stents and these stents have significant clinical advantage in terms of therapeutic superiority, the data is still inadequate. The Committee is of view that there is definitely some technological advancement in this stent, however, there is no major innovation. It is also noted that each and every new stent, has some technological advancement over its previous or other stents which may, as claimed, have some benefit. However this has not shown to have major clinical significance and statistically superior therapeutic outcome. Hence, the Committee recommends that separate pricing for the stents-Synergy may not be considered. The Committee also noted that the issue of different stents is also being considered by the M/o Health & Family Welfare, thus, it is prudent to refer the case to M/o Health & Family Welfare alongwith the above observations, for taking appropriate action in the matter.

i. Stents- Promus Premier Everolimus Eluting Coronary Stent system (Boston Scientific).

The issue of Stents was discussed in detail. The company made the presentation before the Committee. The Committee observed that there has been technological advancement which the company claimed has resulted in less incidence of stent thrombosis and more procedure success as compared to their/other newer available stents. To conclusively say that there is a significant difference in terms of adverse impacts as compared to their/other newer currently available stents and these stents have significant clinical advantage in terms of therapeutic superiority, the data is still inadequate. The Committee is of view that there is definitely some technological advancement in this stent, however, there is no major innovation. It is also noted that each and every new stent, has some technological

advancement over its previous or other stents which may, as claimed, have some benefit. However this has not shown to have major clinical significance and statistically superior therapeutic outcome. Hence, the Committee recommends that separate pricing for the stents- Promus may not be considered. The Committee also noted that the issue of different stents is also being considered by the M/o Health & Family Welfare, thus, it is prudent to refer the case to M/o Health & Family Welfare alongwith the above observations, for taking appropriate action in the matter.

j. Stents- Albuminus DES+ - An Abluminal coated Sirolimus Eluting Coronary Stent system and Focus np DES+ - An Abluminal coated nanocarrier based Sirolimus Eluting Coronary Stent system

The Committee observed that Drug Eluting Stent (DES) is a complex device consisting of several variable components such as metals or polymer as base, thickness, drugs used, specification and drugs/stents delivery system, etc. Each permutation & combination has potential to generate different patents. Moreover, in this case, the patent is applied for in India and yet to be granted. Hence, the Committee recommends that exemption of stents- Albuminus DES+ and Focus np DES+ and under para 32 of DPCO, 2013 may not 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