

National Pharmaceutical Pricing Authority

Subject: Minutes of the 9th meeting of Standing Committee of Experts held on 13.10.2017 under Para 15 of the DPCO 2013

9th 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. Naval K. Vikram, Professor, Deptt of Medicine, AIIMS
3. Prof. D P Pathak, Director, DIPSAR
4. Sh. P. K. Abdul Kareem, Addl. Economic Advisor, Deptt of Economic Affiars, MoF
5. Sh Chandrasekhar Ranga, Dy. Drug Controller, DCGI
6. Sh. Rakesh Pandey, Dy. Director, O/o the CAC, Deptt of Expenditure, MoF
7. Sh. A P S Sawhney, Director (Pricing), Convenor.
8. Sh. Baljit Singh, Assistant Director (Pricing), NPPA
9. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA.

At the outset, the members of the committee were apprised about the decisions taken in its previous meetings and action taken by the NPPA in this regard. Thereafter, the Committee took up the agenda circulated for its consideration. The item-wise deliberation and decision are minuted as under:

1. Soft Gelatin Capsule capsule Omega 3- Acid Ethyl Esters -60BP providing Docosahexonic acis 90mg, Mecobolamin acid 60mg, Pyrodoxine 3mg, Folic Acid 1.5 mg, Vitamin E 25IU , Vitamin C 100g, Zinc Sulphate 15mg, Sodium slenite 60mg of M/s Magnet Labs Pvt Ltd. (Marketer) and M/s Mankind Pharma Ltd. (Manufacturer) (Application received on 03.5.2016):-

The Committee deliberated the matter in details and directed that the information relating to composition wise cost breakup be obtained from the applicant company.

2. Brizolamide 1% and Timolol 0.5% eye drops in 5ml vial of Ajanta Pharma Ltd. (Application received on 30.5.2016):-

The information regarding cost of the active ingredients for the subject formulation is yet to be received from the applicant company. Hence, the Committee decided to defer the matter and reminder be issued to the company.

3. Sioneuron F Tablet containing Multivitamins of M/s Albert David Ltd. (Application received on 14.7.2016):-

The information as sought from DCG(I) is yet to be received. Hence, the Committee decided to defer the matter and reminder be issued to the company.

4. Vaccine Easy four-TT PFS containing Diphteria Toxid 20LF 30 IU, Tetanus Toxid 7.5LF 60IU, Inactivated w-B pertussis bulk 12IOU 4IU, Hib PRP conjugated with carrier

protein Tetanus Toxoid 10 µg etc fully Liquid of M/s Panacea Biotech Ltd. (Application received on 22.7.2016).

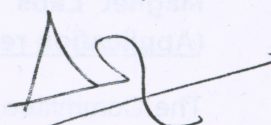
The information regarding cost breakup/justification of Rs. 530 for the existing product and other requisite details is yet to be received from the applicant companies. Hence, the Committee decided defer the matter and reminder be issued to the company.

5 & 6. Cybex MV 40.2 each tablet contain Metformin HCL 500mg + Gliclazide 40mg + Voglibose 0.2mg and Cybex MV 40.3 each tablet contain Metformin HCL 500mg + Gliclazide 40mg + Voglibose 0.3mg by Eris Lifesciences Ltd. (WPA case received on 14.12.2016).

The Committee deliberated the issue with reference to the letter dated 8-Sep-2017 of DCGI and noticed that the formulation is banned by Ministry of Health and Family welfare as confirmed by the DCGI. However, various stakeholders filed various writ petitions in various high courts across the country and said notification was quashed by Hon'ble High court of Delhi vide its order dated 1.12.2016. Government has already challenged the order of Delhi High court before Supreme Court of Delhi by way of SLP. Accordingly, the Committee recommended that the price of the formulation to be kept in abeyance till the outcome of the litigation.

7. Seven number of application for the formulation containing Sofosbuvir 400mg and Velpatasvir 100mg for price fixation.

The authority discussed the various options viz. (i) Ceiling price of Sofosbuvir 400mg under DPCO 2013 plus worked out price for the Velpatasvir 100mg (ii) Price computed based on formula similar para 4 or 5 of the DPCO 2013 for latest available data, (iii) the lowest price claimed by the various applicant companies for the pack. The authority after considering the various options recommended the retail price of Rs. 15,625/- plus GST for 28 tablets pack being the lowest claimed price (exclusive of GST) by Abbott India Limited.


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

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All members of the Committee