## National Pharmaceutical Pricing Authority

Subject: Minutes of the 7<sup>th</sup> meeting of Standing Committee of Experts held on 30.01.2017 under Para 15 of the DPCO 2013

A meeting of the "Standing Committee" was held on 30.01.2017 under Chairpersonship of the Sh. Kalyan Nag, Adviser (Cost), in the Conference Room of NPPA. The Chairperson extended warm welcome to the members who participated. The quorum was present to conduct the meeting. The following members/officers attended the meeting:-

- 1. Dr. Y. K. Gupta, Prof. & Head, Deptt of Pharmacology, AIIMS -Member.
- 2. Dr. Naval K Vikram, Prof., Deptt of Medicine, AIIMS, New Delhi –Member.
- 3. Sh. Chandrasheka Ranga, Dy. DC (I), O/o the DCGI-Member.
- 4. Sh. Rakesh Pandey, Dy. Director, O/o the CAC, Deptt of Expenditure, MoF-Member.
- 5. Sh. A.K.Khurana, Director (Pricing), Convenor.
- 6. Sh. Baljit Singh, Assistant Director (Pricing), NPPA.
- 7. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA.
- 2. At the outset, the members of the committee were apprised about the provisions of new drug under paras 5 and 15 of DPCO, 2013 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)
- (i). The Committee decided that a letter may be issued to DCGI to sought clarification/confirmation as to whether the subject formulation has been approved by o/o DCG(I) or not.
- (ii). The Committee also directed to obtain the prices of other ingredients in addition to that of Omega 3 of same strength in the subject formulation.
- 2. Brizolamide 1% and Timolol 0.5% eye drops in 5ml vial of Ajanta Pharma Ltd. (Application received on 30.5.2016):-

The Committee directed to work out the price of container/packaging of Brizolamide 1% and Timolol 0.5% eye drops in 5ml vial separately for factoring while calculating the proposed retail price.

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

The Committee decided that a letter may be issued to DCGI to sought clarification/confirmation as to whether the subject formulation has been approved by o/o DCG(I) or not.

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 Toxid 10 μg etc fully Liquid of M/s Panacea Biotech Ltd. (Application received on 22.7.2016):-

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The Committee discussed the issue in detail and decided that the retail price of the subject formulation may be considered but not exceeding the same of competitors' products like QUADRVOX and COMVAC 3 + BioHib available in the market and may be fixed as per para 5 of DPCO, 2013 without differentiating between in pre-mixing/two vials and single vial as there is no significant therapeutic advantage in single vial over pre-mixing/two vials.

5&6. Rabishield Rabies Human Monoclonal Antibody (rDNA) in 250IU(2.5ml) and 100IU(2.5ml) pack in M/s Serum Institute of India Ltd. (Application received on 01.11.2016):-

The Committee in-principle recommended the ceiling/retail price fixation on the benchmark of ceiling price of Anti-rabies immunoglobulin 150IU/ML. Since the ceiling price of Anti-rabies immunoglobulin 150IU is yet to be revised under NLEM 2015, the Committee decided to defer the fixation of ceiling/retail price of the subject formulation till the ceiling price revision of Anti-rabies immunoglobulin150IU under NLEM, 2015.

3. 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