

By Special Messenger /Speed Post

F. No. 19(15)/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/पांचवीं मंजिल 5<sup>th</sup> / 3<sup>rd</sup> Floor,  
आई.एम.सी.ए. सांस्कृतिक केन्द्र भिडिंग  
YMCA Cultural Center Building,  
1, जय सिंह रोड, नई दिल्ली-110001  
1, Jai Singh Road, N. Delhi - 110001.  
दिनांक :- 12.5.2017

**OFFICE MEMORANDUM**

**Subject: 8<sup>th</sup> meeting of the Standing Committee of Experts under para 5 & 15 of DPCO, 2013.**

The undersigned is directed to forward herewith the Minutes of 8<sup>th</sup> Meeting of Standing Committee of Experts (held on 02.5.2017 & 04.5.2017) under para 5 & 15 of Drugs (Prices Control) Order, 2013. This is for your information and necessary action please.

  
(A. K. Khurana)  
Director (Pricing)

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 Wakade, DIPSAR.
7. Sh. Rakesh Pandey, Dy. Director, O/o the CAC, Deptt of Expenditure, MoF.
8. Dr. Ravi Kant Sharma, ADC, Office of the DCGL.

Copy for information to:

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

F.No. 19(15)/2013/DP/NPPA/Div.II  
National Pharmaceutical Pricing Authority

**Subject: Minutes of the 8<sup>th</sup> meeting of Standing Committee of Experts held on 02.5.2017 and 04.5.2017 under Para 15 of the DPCO 2013**

I. A meeting of the "Committee of Experts" was held 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 Affairs, 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 the decision 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 Oega 3- Acid Ethyl Esters -60BP providing Docosahexonic acid 90mg, Mecobolamin acid 60mg, Pyrodoxine 3mg, Folic Acid 1.5 mg, Vitamin E 25IU , Vitamin C 100g, Zinc Sulphate 15mg, Sodium selenite 60mg of M/s Magnet Labs Pvt Ltd. (Marketer) and M/s Mankind Pharma Ltd. (Manufacturer) (Application received on 03.5.2016):-**

The Committee sought for information regarding the approval given by DCGI. Accordingly, a letter was issued to DCGI to furnish requisite information which is still awaited. Hence, the Committee decided to defer the case and DCGI be reminded to furnish the requisite information.

**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 obtain information from the company regarding the cost of active ingredients for the subject formulation, duly certified by the Chartered/Cost & Management Accountant.

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

The Committee sought information regarding the approval given by DCGI. Accordingly, a letter was issued to DCGI to furnish requisite information which is still awaited. Hence, the Committee decided to defer the case and DCGI be reminded to furnish the requisite information.

**4. Vaccine Easy four-TT PFS containing Diptheria 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):-**

The Committee decided to defer the issue for next meeting.

**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 deliberated on the issue in details and recommended for consideration and approval of the Authority the retail price of Rs. 22656.60 for 250IU(2.5ml)/pack and Rs. 9062.64 for 100IU(2.5ml)/pack.

**7. Agenda nos. 7 to 9 – Deferred for next meeting.**

II. The 8<sup>th</sup> meeting of the "Committee of Experts" was continued on 04.5.2017 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. Sharad Wakode, DIPSAR
3. Dr. Ravi Kant Sharma, ADC, Office of the DCGI
4. Sh. A.K. Khurana, Director (Pricing), Convenor.
5. Sh. Baljit Singh, Assistant Director (Pricing), NPPA
6. 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 remaining agenda circulated for its consideration. The item-wise deliberation and decision are minuted as under:

**4. Vaccine Easy four-TT PFS containing Diptheria 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):-**

The Committee reiterated 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 pre-mixing/two vials and single vial as there is no significant therapeutic advantage in single vial over pre-mixing/two vials. Further, the Committee directed to obtain the following information from the concerned companies:

- i. The cost break-up/justification of Rs. 530 at which the applicant company was selling earlier.
- ii. The PTR and MAT value of COMVAC 3+ BioHib from the manufacturer/marketing company.

**7. Various packs of Paracetamol Injection 150mg/ml of 0.5ml, 1ml, 3ml, 4ml, 5ml, 7ml of M/s Themis Medicare Ltd. (Application received on 11.7.2016).**

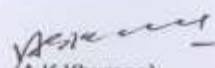
The Committee recommended prices of 0.5ml, 1ml, 3ml, 4ml, 5ml and 7ml pack of Paracetamol Injection 150mg/ml as ceiling price for consideration and approval of Authority, as detailed below:-

Formulation	Pack-size	Recommended Ceiling Prices under Pronab Sen Committee formula applying 0.7 as constant (incl. WPI) (Rs.)
Paracetamol 1.5% w/v (Paracetamol 150mg/ml)	0.5 ml (or 75mg)	2.90
	1.0 ml (or 150mg)	3.97
	3.0 ml (or 450mg)	8.24
	4.0 ml (or 600mg)	10.37
	5.0 ml (or 750mg)	12.51
	7.0 ml (or 1050mg)	16.78

**8&9. Cyblex MV 40.2 each tablet contain Metformin HCL 500mg + Gliclazide 40mg + Voglibose 0.2mg and Cyblex MV 40.3 each tablet contain Metformin HCL 500mg + Gliclazide 40mg + Voglibose 0.3mg by M/s Eris Lifesciences Ltd. (WPA case received on 14.12.2016):**

The Committee directed to write to DCGI to examine the rationale of these three drug combination of anti-diabetic formulation having Metformin HCL 500mg + Gliclazide 40mg + Voglibose 0.2mg/0.3mg for sale in domestic market of India and to furnish copy of permission/licence granted to the company i.e. M/s Eris Lifesciences Ltd.

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

  
(A.K. Khurana)

Director (Pricing)

Copy to:

All members of the Standing Committee