

**F.No. 12(7)/2017/DP/NPPA/Div.II/ Vol-II**  
**National Pharmaceutical Pricing Authority**

**Subject: Minutes of the 10th meeting of Multidisciplinary Committee of Experts held on 21.05.2019 at 11:00 AM in NPPA**

10th meeting of the "Multidisciplinary Committee of Experts" was held on 21.05.2019 under the Convenorship of the Sh. Kalyan Nag, Adviser(Cost), in the Conference Room of NPPA. The following members/officers attended the meeting:-

1. Dr.C.D.Tripathi, Head Department of Pharmacology, VMMC & Safdarjung Hospital.
2. Dr. K. Bangarurajan, Jt. Drugs Controller, CDSCO
3. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission
4. Dr. Monika Pahuja, Scientist-C, ICMR, New Delhi.
5. Dr. Ujjal Kolhe, Asstt Professor, NIPER, Rae Bareli
6. Shri APS Sawhney, Director (Pricing), NPPA
7. Shri Manoj Kr. Singh, Dy. Director (Overcharging), NPPA
8. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA
9. Sh. Prakash Hemani, Assistant Director (Pricing), NPPA

The following special invitees were also attended the meeting:

1. Dr. Janak Raj, Sr. MS, IGMC, Shimla
2. Dr. Rama Wasan, HOD, Anaesthesia, VMMC & Safdarjung Hospital
3. Dr. Surinder Singh, Prof & Head, Anaesthesia, IGMC, Shimla

**Agenda No. 1 - JENVAC Injection: Each dose of 0.5ml contains: Purified, Inactivated Japanese Encephalitis Virus Protein (JEV Strain 821564-XY) NLT 5.0 mcg, Aluminum (Al+++ ) as Aluminum Hydroxide gel 0.25 mg, Thiomersal (as Preservative) IP 0.025mg & Phosphate Buffered Saline qs to 0.5 ml Injection Manufactured and marketed by M/s Bharat Biotech International Limited.**

The Committee deliberated upon the matter in details and noted the reply received from Immunisation Division, Ministry of Health and Family Welfare. The Committee observed that under routine immunization of all types of Japanese Encephalitis (JE) vaccine, two dosages are required to be given. Accordingly, the Committee recommended to reject the retail price application of Purified, Inactivated Japanese Encephalitis Virus Protein (JEV Strain 821564-XY) NLT 5.0 mcg, Aluminum (Al+++ ) as Aluminum Hydroxide gel 0.25 mg, Thiomersal (as Preservative) IP 0.025mg & Phosphate Buffered Saline qs to 0.5 ml Injection Manufactured and marketed by M/s Bharat Biotech International Limited.

**Agenda No. 2 – Application for grant of separate price/ special price for "Synchrobreathe inhaler device" under the provision of Para 11(3) or para 32(3) of DPCO 2013**

The Committee deliberated upon the matter in details and the documents submitted by the company. M/s Cipla Ltd also provided demonstration and presentation with respect to their product 'Synchrobreathe inhaler device'. However, due to some further clarification being



sought by one of the member, the matter was deferred for further discussion the in next meeting.

**Agenda No. 3 - Representation of M/s Biological E.Ltd for separate pricing of vaccines having new drug delivery system- Pre filled Syringe (PFS) packs**

The Committee deliberated upon the matter in details and noted that the prefilled syringe is a minor modification which will ease the drugs administration and have no significant clinical advantage." Accordingly, the Committee recommended that no separate price be given for PFS.

**Agenda 4 - Due deliberation in respect of ceiling price notified by the NPPA for Oxygen Gas is being supplied to the various Hospitals through composite contract - reg.**

The Committee deliberated upon the matter in details and noted the representations made by the All India Industrial Gases Manufacturers Association (AIIGMA). The AIIGMA in its representation stated that the price provided by NPPA is not remunerative in comparison to the cost of production/marketing. Further, they have also expressed that the oxygen gases are supplied in liquid form as well as gaseous form, in different sizes of cylinders as well as by setting up plants at the premises of the buyers and their price differs as per the physical form, size of cylinder as well as mode of supply, terms of contracts and applicable taxes and electricity tariff of the state. The Committee also noted the views of Medical Superintendent and anesthetist of Safdarjung hospital and IGMC, Shimla where they expressed concerns about institutional procurement of medical oxygen in a composite contract through tender/ other process. After due deliberation, the committee requested AIIGMA and IGMC, Shimla to submit their written submission with their concerns and views in the matter by 24<sup>th</sup> May, 2019. The Committee further directed NPPA to bring the matter for deliberation and decision in the next Meeting of the Committee.

**Agenda No 5: Overcharging cases in respect of the formulation "Cloxacillin based formulations Kloxx Injection 500mg, Baxin Inj 1gm (1000 mg), Baxin Inj 500mg, Baxin Inj 250mg, Baxin Kid Tab"reg**

The reply from FDA, Gujarat is still awaited, therefore, the Committee decided to defer the same.

**Agenda No 6: Retail price fixation under Para 5 of DPCO, 2013 for M/s Lupin Limited (marketer) and M/s Akums Drugs and Pharmaceuticals Limited (manufacturer)**

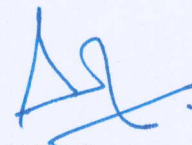
The Committee deliberated upon the issue in details and observed that the formulation Travoprost 40 mcg+ Timolol Maleate 5 mg eye drops with and without preservative are pharmacologically equivalent. Accordingly, the Committee recommended no separate retail price for Travoprost 40 mcg+ Timolol Maleate 5 mg eye drops (preservative free) for M/s Lupin Limited (marketer) and M/s Akums Drugs and Pharmaceuticals Limited (manufacturer)

**Agenda No 7: Retail price fixation under Para 5 of DPCO, 2013 for M/s Emcure Pharmaceuticals Limited (Manufacturer and marketer)**



The Committee deliberated upon the matter in details and observed that as per the Pharmatrac database, M/s Emcure Pharmaceuticals Ltd is only the manufacturer/ marketer of Dolutegravir 50mg tablet. The Committee directed NPPA to check from DCGI office whether the approval of Dolutegravir 50mg tablet is given to any other manufacturer or not. Accordingly, the matter is deferred.

The meeting ended with a vote of thanks to the Convener.



(APS Sawhney)  
Director (Pricing)

Copy to:

All members of the Committee and special invitees.