

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

Subject: Minutes of the 12th meeting of Multidisciplinary Committee of Experts held on 31.07.2019 at 11:00 AM in NPPA

12th meeting of the “Multidisciplinary Committee of Experts” was held on 31.07.2019 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. Pawan K. Saini, Scientific Officer, Indian Pharmacopoeia Commission
4. Shri APS Sawhney, Director (Pricing), NPPA
5. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA
6. Sh. Prakash Hemani, Assistant Director (Pricing), NPPA

Agenda No. 1 - Application of M/s Glenmark Pharmaceuticals Ltd for separate price of “Budesonide+ Formeterol MDI Digital Inhalation under the brand “Digihaler”

The Committee deliberated upon the matter in details and also noted the earlier decisions of the Committee in this regard. The Committee observed that although the products have no additional therapeutic advantages, however, the presence of digital dose counter would help the patients in getting accurate measurement of dosage, low dose warning LED, end of dose display etc. Thus the Committee is of the opinion that this is an incremental innovation and accordingly recommended that “Budesonide+ Formeterol MDI Digital Inhalation under the brand “Digihaler” may be separately priced.

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 noted that the Dr. Ujjal D. Kolhe, Asstt professor, NIPER, Rae Bareli, remained absent in last two meetings. Therefore, the issues raised by him earlier in the matter could not be discussed resulting in pendency of the matter. Accordingly, the Committee directed that a letter may be sent to Director, NIPER (Rae Bareli) for directing Dr. Ujjal D. Kolhe to attend the next meeting positively so that the pending matter may be discussed and decided. Further, the Committee also suggested to send a copy of the documents received from M/s Cipla Ltd in response to the queries raised by him to Dr. Ujjal D. Kolhe for his comments in the matter.

Agenda No. 3 - Retail price fixation under Para 5 and 15 of DPCO, 2013 for M/s Cipla Ltd (marketer) and M/s Cipla Ltd (manufacturer/ importer)

The Committee deliberated upon the matter in details and noted that the composition of the product of M/s Cipla Ltd is same as that of M/s Lupin Ltd as included in the working sheet uploaded in NPPA’s website. Further, the documents submitted by the M/s Cipla Ltd does not substantiate that the study report pertains to their product. In addition, the product also has no separate license from DCGI as required for a new drug. In view of the above, the Committee did not accept the representation of M/s Cipla Ltd and recommended earlier uploaded ceiling price of Rs. 1.46 per metered dose excluded GST.

Agenda 4 – 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 four companies viz. M/s Aurobindo Pharma, M/s Mylan laboratories Ltd, M/s Cipla Ltd and M/s Natco Ltd have been given license to manufacturer/ market Dolutegavir for public health systems only. Further, as per the documents submitted by M/s Emcure Pharmaceuticals Ltd, they are the only company which is licensed to market Dolutegravir 50 mg tablet in Indian retail market. Therefore, the retail price is required to be calculated as per para 4 of DPCO 2013 only on the basis of price of Dolutegavir 50 mg tablet marketed by Ms Emcure Pharmaceuticals Ltd. Accordingly, the Committee recommended the retail price of Dolutegravir 50 mg + Emtricitabine 200 mg + Tenofovir Alafenamide 25 tablet for M/s Emcure Pharmaceuticals Ltd (manufacturer & marketer) as per the principles of price fixation detailed below:

Computation of Retail Price per Tablet	Source/Method	Tenofovir Alafenamide 25mg + Emtricitabine 200mg + Dolutegavir 50mg (Rs excluding GST)
Composition - Tenofovir Alafenamide 25mg + Emtricitabine 200mg + Dolutegavir 50mg		
a. Tenofovir Alafenamide 25mg + Emtricitabine 200mg Tablet		Note 1
b. Dolutegavir 50mg	As per para 4	89.54
Worked out Retail Price		Note 1 + 89.54
c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		20% of lower of (a) or (b) above
d. Net Retail Price (a+b-c)		Note 1 + 89.54 – (c)
e. Company Claimed Price		172.00
Recommended price		Lower of (d) or (e)

Note 1. With respect to the formulation Tenofovir Alafenamide 25 mg + Emtricitabine 200 mg tablet, the Committee was informed that the retail price as sought by M/s Emcure Pharmaceuticals Ltd is under consideration for price approval. Accordingly, the Committee recommended to consider the retail price as would be given to M/s Emcure Pharmaceuticals Ltd for the formulation of 'Tenofovir Alafenamide 25 mg + Emtricitabine 200 mg tablet' on its approval as price of "a".

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

Sd/-
(APS Sawhney)
Director (Pricing)

Copy to:

All members of the Committee.