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

**Subject: Minutes of the 8th meeting of Multidisciplinary Committee of Experts held on 18.03.2019 at 11:00 AM in NPPA**

8th meeting of the "Multidisciplinary Committee of Experts" was held on 18.03.2019 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. U. D. Kolhe, Asstt Professor, NIPER, Rae Bareli.
4. Dr. Gaurav Pratap Singh, Sr. Scientific Officer, Indian Pharmacopoeia Commission
5. Shri APS Sawhney, Director (Pricing), NPPA
6. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA
7. Sh. Prakash Hemani, Assistant Director (Pricing), NPPA

In addition, the following officials were present as special invitees:

1. Dr. R. S. Gupta, Dy. Director General, NACO
2. Dr. Ramesh Kumar, Director CIO, Safdarjung Hospital

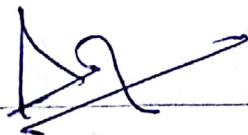
**Agenda No. 1 - Retail Price of each Tablet Contains: Tenofovir Alafenamide Fumarate 25mg Tablet.**

Based on the direction of the Authority, the Committee again deliberated on the issue. The Committee observed that as per para 2(w) of DPCO 2013, "Pharmaeconomics" is defined as "a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another." The Committee also observed that they had earlier recommended the retail prices of this new drugs on the principals of "Pharmaeconomics". Dr. R.S. Gupta, Dy. Director General, National Aids Control Organisation (NACO), attended the meeting as a special invitee stated that Tenofovir Disoproxil Fumarate (TDF), which is in the National Health Program, is choice for new-patient as a first line of treatment whereas Tenofovir Alafenamide Fumarate (TAF) is not in the program. Accordingly, the Committee reiterated its opinion that since the clinical and therapeutic efficacy of Tenofovir 300 mg tablet, which is a scheduled formulation, and Tenofovir Alafenamide Fumarate (TAF) are same, the ceiling price of Tenofovir 300mg tablet at 44.29 per tablet excluding GST may be extended to Tenofovir Alafenamide Fumarate (TAF) tablet 25 mg.

**Agenda No. 2 – Retail Price of JENVAC Injection: Each dose of 0.5ml contains: Purified, Inactivated Japanese Encephalitis Virus Protein (JEV Strain 821564-XY) NLT 5.0mcg, Aluminium (Al+++ as Aluminium Hydroxide gel 0.25mg, Thiomersal (as Preservative) IP 0.025mg & Phosphate Buffered Saline qs to 0.5ml Injection Manufactured and marketed by M/s Bharat Biotech International Limited.**

Since the response is awaited, the Committee decided to defer the matter.

**Agenda No. 3 - Retail Price of each film coated tablet contains: Emtricitabine IP 200mg, Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg (i)**



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**Manufactured by Hatero Labs Pvt Ltd. and Marketed by M/s Cipla Ltd (ii) Manufactured by Mylan Laboratories Ltd and marketed by Mylan Pharmaceuticals Pvt Ltd.**

Based on the direction of the Authority, the Committee again deliberated on the issue. The Committee observed that as per para 2(w) of DPCO 2013, "Pharmaeconomics" is defined as "a scientific discipline that compares the therapeutic value of one pharmaceutical drug or drug therapy to another." The Committee also observed that they had earlier recommended the retail prices of this new drugs on the principals of "Pharmaeconomics". Dr. R.S. Gupta, Dy. Director General, National Aids Control Organisation (NACO), attended the meeting as a special invitee also stated that Tenofovir Disoproxil Fumarate (TDF), which is in the National Health Program, is choice for new-patient as a first line of treatment whereas Tenofovir Alafenamide Fumarate (TAF) is not in the program. Accordingly, the Committee reiterated its opinion that since the clinical and therapeutic efficacy of Tenofovir 300 mg tablet, which is a scheduled formulation, and Tenofovir Alafenamide Fumarate (TAF) 25 mg tablet are the same, the price of tablet containing Emtricitabine 200mg, Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25 mg may be worked out on the basis of data of the formulation Emtricitabine 200mg and Tenofovir (TDF) 300 mg tablet. Accordingly, the price of Emtricitabine 200mg and Tenofovir (TDF) 300 mg tablet worked out to Rs. 55.33 per tablet excluding GST under para 5 of DPCO 2013 based on the data of February 2018, which, the Committee recommended for Emtricitabine 200mg and Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25 mg tablet at Rs. 55.33 per tablet excluding GST.

**Agenda 4 - Each film coated tablet containing Emtricitabine IP 200mg + Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 10mg (i) Manufactured by Hetero Labs Pvt Ltd. and Marketed by M/s Cipla Ltd.**

The Committee deliberated the matter in details and directed to fix retail price by applying the principles of Pronab Sen Committee report based on the recommendation made for retail price fixation of (i) Tenofovir Alafenamide Fumarate (TAF) 25 mg tablet as per Agenda No.1 and (ii) Emtricitabine IP 200mg and Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg tablet as per Agenda No. 3. Accordingly, the Committee recommended the retail price of Emtricitabine IP 200mg + Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 10mg tablet at Rs. 31.17 per tablet excluding GST as detailed below:

Sl. No.	Particulars	Per tablet excluding GST
A.	Recommended retail price of Emtricitabine IP 200mg + Tenofovir Alafenamide 25mg tablet as per Agenda no.3	Rs. 55.33
B.	Recommended retail price of Tenofovir Alafenamide Fumarate 25mg Tablet as per Agenda No. 1	Rs. 44.29
C.	Derived price of Emtricitabine IP 200 mg tablet (A-B)	Rs. 11.04 (Rs. 55.33-Rs.44.29)
D.	Derived retail price of Tenofovir Alafenamide Fumarate 10 mg Tablet by applying Pronab Sen Committee formula to recommended retail price of Tenofovir Alafenamide Fumarate 25mg Tablet as per Agenda no. 1	Rs. 20.13 {Rs. 44.29 = Price of 10 mg (1 + 0.8 (25-10/25) i.e. Rs. 20.13}
E.	Retail price claimed by the applicant company	Rs.80.00 (Rs.2400.00/30 tablet)

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F.	<b>Recommended price of Emtricitabine IP 200mg + Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 10mg tablet (C+D)</b>	<b>Rs. 31.17 (Rs. 11.04 + Rs. 20.13)</b>
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**Agenda No. 5 - Deliberation in respect of ceiling price notified by the NPPA for Oxygen Gas is being supplied to the various Hospitals through composite contract**

The Committee deliberated on the matter and it was decided two anaesthetist and two Medical Superintended, one each from Delhi and Outside Delhi and representative of the All India industrial gases Manufacturers Association (AIIGMA) may be invited for further deliberation on this matter.

**Agenda No. 6 - Request for pricing of M/s Johnson & Johnson's new product ATTUNE S+™ of Tibial Component of Orthopaedic Knee Implant.**

The Committee deliberated the issue in details. Dr. Ramesh Kumar, Director, Central Institute of Orthopaedics (CIO), VMMC & Safdarjung hospital stated that the recent report and publications points about the quality and safety concerns about the products. The product has also hit with several recalls. In view of the above, the Committee recommended that no price revision be allowed to Attune S+ Orthopaedic Knee Implant of M/s Johnson and Johnson and hence the proposal is rejected.

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

  
(APS Sawhney)  
Director (Pricing)

Copy to:  
All members of the Committee and special invitee.