

**National Pharmaceutical Pricing Authority**

**Subject: Minutes of the 6th meeting of Multidisciplinary Committee of Experts held on 15.01.2019 at 11:30 AM in NPPA**

The 6th meeting of the "Multidisciplinary Committee of Experts" was held on 15.01.2019 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. Ms. Rajni Kaul Scientist-G, ICMR, New Delhi.
4. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission
5. Dr. Ujwal D. Kolhe, Asstt Professor, NIPER, Rae Bareli
6. Shri APS Sawhney, Director (Pricing), NPPA
7. Sh. Baljit Singh, Deputy Director (Cost),
8. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA
9. Sh.Prakash Hemani, Assistant Director, NPPA

The members of the Committee then first took up agenda under para 15 of DPCO, 2013. The item-wise deliberation and recommendation, if any, are given as under:

**A. Agenda relating to Para 15 of DPCO 2013.**

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

The Committee deliberated on the issue at length. The Committee is of the opinion that the clinical efficacy of Tenofovir 300 mg tablet which is a scheduled formulation and Tenofovir Alafenamide Fumarate 25 mg tablet are same and hence the Committee recommended to extend the ceiling price of Tenofovir 300 mg tablet at Rs. 44.29 per tablet excluding GST to Tenofovir Alafenamide Fumarate 25 mg tablet.

**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.**

As directed by the committee, NPPA has forwarded the representation of M/s Biological E. Ltd to the applicant M/s Bharat Biotech International Ltd to obtain their comments. Comments of the **Bharat Biotech International Limited** are awaited. NPPA further stated that as directed, after receipt of the comments both the representation of M/s Biological E. Ltd and the comments of M/s Bharat Biotech International Ltd will be sent to Immunization Division of Ministry of Health and Family Welfare to obtain their views. After deliberation, the Committee directed NPPA to give a reminder to M/s Bharat Biotech International Ltd. The Committee further directed NPPA to forward the representation of M/s Biological E. Ltd and the documents submitted along with the application by M/s Bharat Biotech International Ltd to Dr. M. K. Agarwal, Dy. Commissioner, Immunisation Division, Ministry of Health and Family Welfare for his considered opinion in the matter.

**Agenda No. - 3 Retail Price of Jubinerv Capsule each hard gelatine capsule contains: Alpha Lipoic Acid USP 100mg, Methylcobalamin 1500mcg, Vitamin B6 IP 3mg, Folic Acid IP 1.5mg, Benfotiamine 50mg, Biotin USP 5mg, Chromium Picolinate USP eq. to Chromium 200mcg Manufactured by M/s Theon Pharmaceutical Ltd. and marketed by M/s Jubilant Life Sciences Limited**



It was informed to the committee that CDSCO has provided the details of company/companies to whom form 46 were issued for the said product and NPPA has sent a letter to the company to provide the details w.r.t production, sales, PTR & MAT and the name of the party marketing the said product on 14.01.2018. The Committee deliberated on the issue and directed NPPA to obtain the information at the earliest.

**Agenda No. 4 - Retail Price of each hard gelatine capsule contains: Alpha Lipoic Acid USP 100mg, Methylcobalamin 1500mcg, Vitamin B6 IP 3mg, Folic Acid IP 1.5mg, Benfotiamine 50mg, Biotin USP 5mg Manufactured and marketed by M/s KonTest Chemicals Limited**

It was informed to the committee that CDSCO has provided the details of company to whom form 46 were issued for the said product and NPPA has sent a letter to the company to provide the details w.r.t production, sales, PTR & MAT and the name of the party marketing the said product on 14.01.2018. The Committee deliberated on the issue and directed NPPA to obtain the information at the earliest.

**Agenda No. 5. - Retail Price of each film coated tablet contains: Emtricitabine IP 200mg, Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg Manufactured by Hatero Labs Pvt Ltd. and Marketed by M/s Cipla Ltd.**

The Committee deliberated the matter in details and observed that the clinical efficacy of Tenofovir(TDF) 300 mg tablet which is a scheduled formulation and Tenofovir Alafenamide Fumarate 25 mg tablet are same. Therefore, the Committee recommended that 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, Tenofovir (TDF) 300 mg tablet which come to Rs. 55.33 per tablet. Accordingly, the Committee recommended the price at Rs. 55.33 per tablet excluding GST.

**Agenda No. 6. Retail price fixation of Clonazepam IP 0.5 mg, 1 mg and 2 mg Oral Disintegrating Strips under Para 5 of DPCO, 2013 for M/s Alkem Laboratories Ltd (marketer) and M/s Zim Laboratories Ltd (manufacturer/importer)**

The agenda was deferred.

**Agenda No. 7. Retail price of each film coated tablet containing Abacavir 600 mg, Lamivudine 300 mg and Dolutegavir 50 mg manufactured and marketed by M/s Emcure Pharmaceuticals Limited.**

The Committee deliberated the matter in details and recommended the retail formulation of each film coated tablet containing Abacavir 600 mg, Lamivudine 300 mg and Dolutegavir 50 mg at Rs. 157.96 per tablet as detailed below:

Computation of Retail Price per Tablet	Source/Method	Abacavir 600mg, Lamivudine 300mg and Dolutegavir 50mg
Composition - Abacavir 600mg, Lamivudine 300mg and Dolutegavir 50mg		
a. Abacavir (A) + Lamivudine (B) Tablet 600 mg(A)+ 300 mg(B)	Ceiling Price as per SO. 1461(E) dated 02.04.2018	85.53
b. Dolutegavir 50mg	As per para 4	89.54
TOTAL		175.07
c. Less 20% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		17.11
Net Retail Price (a+b-c) excluding GST		157.96
Company Claimed Price		203.00
Recommended price excluding GST		157.96

**B. Agenda relating to Para 11(3&4) of DPCO 2013**

**Agenda No. 1. Review order of Budesonide Inhalation 100mcg/dose; Budesonide Inhalation 200mcg/dose; Budesonide & Foremetrol (Budesonide 100mcg + Foremetrol 6mcg/dose); Budesonide & Foremetrol (Budesonide 200mcg + Foremetrol 6mcg/dose) ; Budesonide & Foremetrol (Budesonide 400mcg + Foremetrol 6mcg/dose), Tiotropium 9 mcg/dose and 18 mcg/dose Inhalation.**


The Committee deliberated the matter in details and agrees that Budesonide is a respiratory medicine and its conventional dosage is 100mcg, 200mcg & 400mcg. This is often given in combination with Formeterol in dose of 6 mcg. There are different delivery systems available for inhalations ranging from simple/conventional inhalation device to metered dose inhaler/dry powder inhaler/digital inhaler and autohaler. There may be other different variants/drug dispensing mechanisms available in the market. They offer technological advantage/ease of administration say in old age/children or patients with poor coordination ability.

The Committee further deliberated that although both MDI and DPI are clinically equivalent but MDI is more commonly used and DPI is mostly used in certain specific conditions and has its own advantages/ease of administration. In case ceiling price of both MDI and DPI are combined together, the ceiling price of MDI will be on the higher side which is against the larger public interest. Therefore, the Committee is opined not to give higher price to more commonly used types of drugs i.e. MDI. Accordingly, the Committee recommended for separate price for MDI and DPI type of inhalers.

**Agenda No 2. Review order in respect of Ringer Lactate Injection filed by Aculife Healthcare Private Ltd (Review Order No. 31015/81/2017-Pricing dated 21.03.2018), Albert David Ltd (Review Order No. 31015/76/2017-Pricing dated 21.03.2018), B.Braun Medical (India) Pvt. Ltd (Review Order No. 31015/84/2017-Pricing dated 21.03.2018), Fresenius Kabi India Private Ltd (Review Order No. 31015/82/2017-Pricing dated 21.03.2018) and Otsuka Pharmaceutical India Private Limited (Review Order No. 31015/79/2017-Pricing dated 21.03.2018)**

All the above five manufacturers made presentation and demonstration before the Committee. The Committee observed that the products of Ringer Lactate of all the five manufacturers have the features like (i) self collapsibility and self- sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels and qualify for separate price as 'Non-glass with special features' similar to the SO 1463(E) dated 2.4.2018. Therefore, the Committee recommended to give separate ceiling price of ringer lactate for each pack-size with 'Non-glass with special features'.

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

  
(APS Sawhney)  
Director (Pricing)

Copy to:

All members of the Committee

