

National Pharmaceutical Pricing Authority

Subject: Minutes of the 5th meeting of Multidisciplinary Committee of Experts held on 14.12.2018 at 11:30 AM in NPPA

5th meeting of the “Multidisciplinary Committee of Experts” was held on 14.12.2018 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. K. Bangarurajan, Jt. Drugs Controller, CDSCO
2. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission
3. Dr. Ujwal D. Kolhe, Asstt Professor, NIPER, Rae Bareli
4. Dr. Monika Pahuja, Scientist –C, ICMR, New Delhi.
5. Shri APS Sawhney, Director (Pricing), NPPA
6. Sh. Baljit Singh, Assistant Director (Pricing), NPPA
7. Sh. Prasenjit Das, Assistant Director (Pricing), 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 Vaccine Easy four-TT PFS containing Diphtheria Toxoid 20LF 30 IU, Tetanus Toxoid 7.5LF 60IU, Inactivated w-B pertussis bulk 12IOU 4IU, Hib PRP conjugated with carrier protein Tetanus Toxoid 10 µg etc fully Liquid of M/s Panacea Biotech Ltd. (Application received on 22.7.2016):-

Although the Committee in its earlier meeting had recommended the retail price of the vaccine at Rs. 583 per pack, subsequently it was noticed by the convenor of the committee that the ceiling price of “DPT+ Hib + Hep B” vaccine (having 5 vaccine combinations) was notified at Rs. 75.38 per 0.1 ml. Therefore, the matter was referred back to the Committee in its present meeting. Accordingly, the Committee again deliberated on the issue and after deliberation recommended the retail price of Rs. 340.15 per 0.5 ml pack as detailed below:

Sl. No	Particulars	Strength	Detailed Workings
1	Ceiling price of “DPT + Hib + Hep B Vaccine “ as per SO No. 1461(E) dtd 02.4.2018 Rs. 75.38 per 0.1 ml	Per 0.1 ml	Rs. 75.38 per 0.1 ml
2	Derived ceiling price of 0.5 ml DPT + Hib + Hep B Vaccine	Per 0.5 ml	Rs. 376.90 (Rs. 75.38 X 5)
3	Ceiling price of Hepatitis B Vaccine as per SO No. 1461(E) dtd 02.4.2018 Rs. 73.50 per ml	Per ml	Rs. 73.50 per ml
4	Ceiling price of Hepatitis B Vaccine	Per 0.5 ml	Rs. 36.75 (Rs.73.50 / 2)
5	Worked out ceiling price for DPT + Hib 0.5 ml (2-4)	Per 0.5 ml	Rs. 340.15

Agenda No. 2 Each Tablet Contains: Tenofovir Alafenamide Fumarate 25mg Tablet

The Committee deliberated on the issue at length. The Committee is of the opinion that Dr. C. D. Tripathi, Head Department of Pharmacology, VMMC & Safdarjung Hospital could not attend the meeting and his views are essential to take any decision in this matter. In view of this, the case is deferred till next meeting.

Agenda No. 3 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.

The Committee deliberated the representation given by M/s Biological E. Ltd with respect to the price of JENVAC injection recommended by Multidisciplinary Committee of Experts in its 4th meeting held on 27.9.2018. The Committee directed NPPA to forward the representation of M/s Biological E. Ltd to the applicant M/s Bharat Biotech International Ltd for their comments. The Committee further directed that after receipt of the comments both the representation of M/s Biological E. Ltd and the comments of M/s Bharat Biotech International Ltd to be sent to Immunization Division and CDSCO of the Ministry of Health and Family Welfare to obtain their views.

Agenda No. 4 Manufactured by M/s Theon Pharmaceutical Ltd. and marketed by M/s Jubilant Life Sciences Limited 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**

The Committee deliberated on the issue and directed NPPA to obtain the list of the companies to whom Form 46 was given by CDSCO with respect subject formulation.

Agenda No. 5 Manufactured and marketed by M/s KonTest Chemicals Limited

Each hard gelatine capsule contains:

**Alpha Lipoic Acid USP 200mg,
Methylcobalamin 1500mcg,
Vitamin B6 IP 3mg,
Folic Acid IP 1.5mg,
Benfotiamine 50mg,
Biotin USP 5mg,**

The Committee deliberated on the issue and directed NPPA to obtain the list of the companies to whom Form 46 was given by CDSCO with respect subject formulation

Agenda No. 6 Manufactured and Marketed by M/s Troikaa Pharmaceuticals Ltd.

20 ml vial of Bupivacaine + Fentanyl

Each ml Contains:

**Bupivacaine Hydrochloride IP 1.00mg eq. to anhydrous Bupivacaine Hydrochloride 0.948mg,
Fentanyl Citrate IP eq. to Fentanyl 2.0mcg**

The Committee after deliberation recommended the retail price of Rs. 71.43 per pack excluding GST as detailed below:

Computation of Retail Price	Source/Method	
20ml Vial		
Each ml Contains: Bupivacaine Hydrochloride IP 1.00mg eq. to anhydrous Bupivacaine Hydrochloride 0.948mg, Fentanyl Citrate IP eq. to Fentanyl 2.0mcg		
a. Bupivaccaine	SO 1461(E) 3.68 for 0.5% applying Pronab Sen Committee# for arriving at 1mg/ml.	1.62
b. Fentanyl	SO 1461(E) 21.31 for 50mcg/ml applying Pronab Sen Committee for arriving at 2mcg/ml.	6.99
Worked out Retail Price per ml		8.61
c. Less 30% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		0.49
Net Retail Price (a+b-c) per ml		8.12
Net Retail Price (a+b-c) for 20 ml pack		162.40
Company Claimed Price		Rs. 71.43 excluding GST
Recommended price		Rs. 71.43 excluding GST

Agenda No. 7 Manufactured and Marketed by M/s Troikaa Pharmaceuticals Ltd.

Each ml Contains:

**Bupivacaine Hydrochloride IP 1.25mg eq. to anhydrous Bupivacaine Hydrochloride 1.185mg,
Fentanyl Citrate IP eq. to Fentanyl 2.0mcg**

The Committee after deliberation recommended the retail price of Rs. 75.89 per pack excluding GST as detailed below:

Computation of Retail Price	Source/Method	
20ml Vial		
Each ml Contains: Bupivacaine Hydrochloride IP 1.25mg eq. to anhydrous Bupivacaine Hydrochloride 1.185mg, Fentanyl Citrate IP eq. to Fentanyl 2.0mcg		
a. Bupivaccaine	SO 1461(E) 3.68 for 0.5% applying Pronab Sen Committee# for arriving at 1.25mg/ml.	1.75

b. Fentanyl	SO 1461(E) 21.31 for 50mcg/ml applying Pronab Sen Committee for arriving at 2mcg/ml.	6.99
Worked out Retail Price per ml		8.74
c. Less 30% of the lowest of (a) and (b) similar to formula recommended in the Pronab Sen Committee report		0.52
Net Retail Price (a+b-c) per ml		8.22
Net Retail Price (a+b-c) for 20ml pack		164.40
Company Claimed Price		Rs. 75.89 excluding GST
Recommended price		Rs. 75.89 excluding GST

$$\#P(s) = P^* \cdot [1 + a \cdot \{(s - s^*)/s^*\}]$$

Where: P(s) = price ceiling for strength s

P* = price ceiling for reference strength

s = strength in terms of API content

s* = reference strength a = constant such that 0 < a < 1

Agenda No. 8 **Manufactured by Hetero Labs Pvt Ltd. and Marketed by M/s Cipla Ltd.**

Each film coated tablet contains:

Emtricitabine IP 200mg,

Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg

Claimed price : MRP Rs. 2500 per 30 tablets.

The agenda item was deferred.

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

Agenda No 1. 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)

Due to paucity of time, the agenda item was deferred.

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

(APS Sawhney)
Director (Pricing)

Copy to:

All members of the Committee