

National Pharmaceutical Pricing Authority

Subject: Minutes of the 7th meeting of Multidisciplinary Committee of Experts held on 07.02.2019 at 11:00 AM in NPPA

7th meeting of the "Multidisciplinary Committee of Experts" was held on 07.02.2019 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. Vijay Kumar, Scientist-G, ICMR, New Delhi.
4. Dr. Shashi Bhusan, Sr. Scientific Officer, Indian Pharmacopoeia Commission
5. Shri APS Sawhney, Director (Pricing), NPPA
6. Sh. Baljit Singh, Deputy Director (Cost)
7. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA

Agenda No. 1 – Application of M/s Meril Life Sciences Pvt Ltd for exemption under para 32 (ii) of DPCO, 2013 for their product Sirolimus Eluting BioResorbable vascular scaffold system (MeRes 100).

The committee deliberated the issue in details and observed that the company has submitted the following documents:

- (i). Copy of patent certificate no. 296768 dated 14.05.2018 issued to M/s Meril Life Sciences Pvt Ltd by The Patent Office, Government of India for "annealing process for bioabsorbable stent".
- (ii). DCGI vide its letter no. 4-MD/CT-108/2013-DC dated 19.04.2017 conveyed approval stating that "Sirolimus Eluting BioResorbable vascular scaffold system (MeRes 100)" falls under new drugs as per Rule 122E of Drugs and Cosmetic Rules, 1945.

The committee found that the submission of above documents meets the requirements of para 32(ii) of DPCO, 2013.

Agenda No. 2 – Application of M/s Sun Pharmaceutical Industries Ltd for exemption under para 32 of DPCO, 2013 for their product Gemcitabine Hydrochloride injection 10mg/ml (Ready to use infusion bags 1200mg/120ml, 1400mg/140ml and 1600mg/160ml).

The committee deliberated the issue in details and observed that the company has submitted the following documents:

- (i). Copy of patent certificate no. 296771 dated 14.05.2018 issued to M/s Sun Pharmaceutical Industries Ltd by The Patent Office, Government of India for "Ready to infuse Gemcitabine solution".
- (ii). DCGI vide its letter no. 12-01/18-DC (Pt.-179) dated 08.08.2018 conveyed approval stating that "ready to use infusion gemcitabine HCl injection 10mg/ml (ready to use infusion 1200mg/120ml, 1400mg/140 ml and 1600mg/160ml) falls under new drugs as per Rule 122E of Drugs and Cosmetic Rules, 1945.

The committee found that the submission of above documents meets the requirements of para 32(ii) of DPCO, 2013

Agenda No. 3 - Retail Price of each Tablet Contains: Tenofovir Alafenamide Fumarate 25mg Tablet.

The Committee deliberated on the representations of the various applicant companies received by NPPA against the price approved by the Authority (yet to be notified) for the above said formulation

on the basis of recommendation by the Committee of Expert in its meeting held on 15.01.2018. On examination of the issue, the committee opined that their earlier recommendation was made on scientific basis by comparing therapeutic value of one pharmaceutical drug to another as per the provisions of DPCO, 2013 i.e. rightly gave the same price of Tenofovir Alafenamide Fumarate 25mg Tablet against Tenofovir (TDF) 300mg tablet. The Committee reiterate their earlier recommendations of the price of Rs. 44.29 Per table for Tenofovir Alafenamide Fumarate 25mg Tablet.

Agenda No. 4 – 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 and comments of the M/s Bharat Biotech International Limited to Immunization Division of Ministry of Health and Family Welfare to obtain their views. However, the comments of Immunization Division of Ministry of Health and Family Welfare are still awaited. The committee directed NPPA to send a reminder to Immunization Division of Ministry of Health and Family Welfare to expedite their response.

Agenda No. 5 - Retail Price of Jubinerv hard gelatine capsule manufactured by Theon Pharmaceuticals Ltd and marketed by Jubilent Life Sciences Ltd.

The committee deliberated on the issue and noted that main ingredient (API) in the formulation is Methylcobalamin 1500mcg and recommended that the price of this formulation may be fixed under para 5 on the basis of similar drugs having Methylcobalamin 1500mcg.

Agenda No. 6 - Retail Price of each hard gelatine capsule contains: Alpha Lipoic Acid USP 00mg, 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

The committee deliberated on the issue and noted that main ingredient (API) in the formulation is Methylcobalamin 1500mcg and recommended that the price of this formulation may be fixed under para 5 on the basis of similar drugs having Methylcobalamin 1500mcg.

Agenda No. 7 - Retail Price of each film coated tablet contains: Emtricitabine IP 200mg, Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg (i) 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.

The committee deliberated on the representations of the M/s Cipla Ltd received by NPPA against the price approved by the Authority (yet to be notified) for the above said formulation on the basis of recommendation by the Committee of Expert in its meeting held on 15.01.2018. However, the committee stands by its earlier decision as detailed in agenda no. 1 and recommended the price of Rs. 55.33 Per table for Emtricitabine IP 200mg + Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg tablet. Further, the Committee recommended to extend the same price for the said formulation manufactured by Mylan Laboratories Ltd and marketed by Mylan Pharmaceuticals Pvt Ltd.

Agenda No. 8. 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 Committee deliberated on the issue and observed that NPPA has already notified the ceiling / retail price for Ondansetron 4mg & 8 mg tablet and Ondansetron 4mg & 8 mg Orally Disintegrating Strips (ODS). The Committee also observed that NPPA had also notified the ceiling price of Clonazepam 0.5 mg and 1 mg tablet. Accordingly, the Committee decided that for fixing the retail price of Clonazepam IP 0.5 mg and 1 mg Oral Disintegrating Strips



(ODS), NPPA may apply percent price difference between price notified for Ondansetron ODS (4mg and 8 mg) and Ondansetron tablet of (4mg and 8mg). Further for fixation of retail price of Clonazepam 2 mg ODS, NPPA may apply Pronob Sen Committee formula on the derived price of Clonazepam 1 mg ODS. Accordingly, NPPA worked out the price as under

Formulation	Tablet	Worked out price	Company claimed price
Clonazepam 0.5mg Orally Disintegrating Strip	Rs. 2.92/ tablet SO. 1461(E) dated 02.4.2018	Worked out price - Rs. 5.33/ODS {Rs. 2.92 X 1.8274 (avg %age increase)}	Claim by the company Rs. 15/ODS (Rs. 13.39/strip without GST)
Clonazepam 1mg Orally Disintegrating Strip	Rs. 3.97/ tablet SO. 1461(E) dated 02.4.2018	Worked out price - Rs. 7.25/ODS {Rs. 3.97 X 1.8274 (av %age increase)}	Claim by the company Rs. 20/ODS (Rs. 17.85/ strip without GST)
Clonazepam 2mg Orally Disintegrating Strip		Based on Pronob Sen Committee for additional strength 80% increase may be given for Additional strength. Worked out price – Rs. 7.25 + Rs. 7.25 X80% =Rs. 13.05/ODS	Claim by the company Rs. 25/ODS (Rs. 22.32/strip without GST)

The recommended price of Clonazepam 0.5 mg, 1mg and 2 mg ODS was Rs. 5.33/strip, Rs. 7.25/strip and Rs. 13.05/strip excluding GST respectively.

Agenda No. 9 - retail Price fixation of Diclofenac Potassium 50mg + Chlorzoxazone USP 500 mg film coated tablet under para 5 of DPCO, 2013 for M/s Win Meicare Pvt Ltd (marketer) and M/s G.S. Pharmbutor Pvt Ltd (manufacturer)

The Committee after deliberation recommended the retail price of Rs. 9.28 per Tablet excluding GST as detailed below:

Computation of Retail Price per Tablet		
DICLOFENAC + CHLORZOAZONE 50/500 MG Tablets	Source/Method	
DICLOFENAC + PARACETAMOL + CHLORZOAZONE 50/500/500 MG Tablets	Worked out	9.96
Less: 80% of the Paracetamol 500 Ceiling price 0.85 x 80%	As per para 4	0.68
Worked out Retail Price per tablet		9.28
Company Claimed Price		14.73
Recommended price		9.28

Agenda No. 10 – Retail Price Fixation of Clobazam Oral suspension BP 2.5 mg/ml under para 5 of DPCO, 2013 for M/s Intas Pharmaceuticals Ltd (marketer/manufacturer)

The Committee after deliberation recommended the retail price of Rs. 2.54 per ml excluding GST as detailed below:

Computation of Retail Price per ml	
Worked out price of the for 1mg/ml for May 2018	1.24 per ml

Applying Formula of Pronab Sen committee Rs. [1.24 +1.24 * 0.7(2.5-1)/1]	2.54 per ml
Company Claimed Price	Rs. 2.9167 per ml (Rs. 350/120 ml)
Recommended price	Rs. 2.54 per ml


Agenda No. 11 – Request of pricing of new product ATTUNE S+ TM of Tibal Component of Orthopaedic knee implant of M/s Johnson and Johnson Pvt. Ltd.

The matter was deliberated in the meeting and it was decided that the subject expert Dr. Rajesh Malhotra, Head of Department of Orthopaedics, AIIMS, New Delhi or Dr. Ramesh Kumar, Central Institute of Orthopaedics, Safdarjung Hospital may be invited and co-opted for deliberation on this matter.

Agenda No. 12 – 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 on the matter and observed that the matter is administrative in nature and hence the matter is not within the purview of the Multidisciplinary Committee of Experts for comments.

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



(APS Sawhney)
Director (Pricing)

Copy to:

All members of the Committee