

National Pharmaceutical Pricing Authority

**Subject: Minutes of the 2<sup>nd</sup> meeting of Multidisciplinary Committee of Experts held on 25.5.2018 at 11:00 AM in NPPA**

2<sup>nd</sup> meeting of the "Multidisciplinary Committee of Experts" was held on 25.5.2018 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. Saranjit Singh, Professor & Head, NIPER, SAS Nagar (Member)
2. Dr. Vijay Kumar, Scientist G & Head (BMS), ICMR, New Delhi (Member)
3. Dr. K. Bangarurajan, Jt. Drugs Controller, CDSCO
4. Dr. C. D. Tripathi, Director-Professor, Deptt of Pharmacology, VMMC & Safdarjung Hospital
5. Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission
6. Sh. Baljit Singh, Assistant Director (Pricing), NPPA
7. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA

At the outset, the Convenor extended warm welcome to the members and explained to them the purpose of the Committee, as mandated in DPCO 2013. After, as decided in the 1<sup>st</sup> meeting of the multidisciplinary Committee of Experts, Dr. C. D. Tripathi, Director-Professor, Dept of Pharmacology, VMMC & Safdarjung Hospital and Dr. Jai Prakash, Sr. Principal Scientific Officer, Indian Pharmacopoeia Commission was co-opted as Committee members. The members were provided a copy of DPCO, agenda papers, and also all other supporting documents. The salient features of DPCO 2013 were also deliberated, it being the first meeting for some of the members.

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. 1M/s Pure and Cure Healthcare Pvt. Ltd. and marketed by M/s Jenburkt Pharmaceuticals Ltd. Nervijen D3 tablet Each coated tablet contains: Alpha Liopic Acid 200mg Vitamin D3 1000 IU Pyridoxine HCl 3mg Mecobalamin 1500mcg Folic Acid 1.5mg Biotin 200mcg. (Application received on 18.7.2016)**

1. The worked out retail prices for hard gelatin capsule containing Alpha Lipoic Acid USP 100mg, Mecobalamin IP 1500mcg, Pyridoxine Hydrochloride IP 3mg, Vitamin D3 (As Stabilized) 1000IU, Folic Acid IP 1.5mg is as under:-

Computation of Retail Price per Tablet	Source/Method	Omegaful Capsule
Composition - Each coated tablet contains: Alpha Liopic Acid 200mg Vitamin D3 1000 IU Pyridoxine HCl 3mg Mecobalamin 1500mcg Folic Acid 1.5mg Biotin 200mcg		

a. Notified price of formulation specified in the notification for 10 tablet	S.O. No. 2458(E) dated 24.09.2009 (DPCO'1995)	7.62
b. Total ceiling price Adjustment for 10 tablet	S.O. No. 2458(E) dated 24.09.2009 (DPCO'1995)	9.63
Worked out Retail Price for 10 tablet under DPCO 1995		17.25
Annual increase of 10% as specified under para 10 of DPCO 2013 for 6 years.(i.e 6 times)		17.25X(1.1) <sup>6</sup>
Worked out Retail price for 10 tablet under DPCO 2013		30.56
Worked out Retail price per tablet under DPCO 2013	1 tablet	3.06
Company Claimed Price	1 tablet	10.80
Recommended price	1 tablet	3.06

2. After deliberations, the Committee decided to recommend the worked out retail price, being lower, at Rs. 3.06 per tablet.

**Agenda No. 2 Soft Gelatin Capsule capsule Omega 3- Acid Ethyl Esters -60BP providing Docosahexonic acid 90mg, Mecobolamin acid 60mg, Pyrodoxine 3mg, Folic Acid 1.5 mg, Vitamin E 25IU , Vitamin C 100g, Zinc Sulphate 15mg, Sodium selenite 60mg of M/s Magnet Labs Pvt Ltd. (Marketer) and M/s Mankind Pharma Ltd. (Manufacturer) (Application received on 03.5.2016)**

1. The worked out retail prices for Soft Gelatin Capsule capsule Omega 3- Acid Ethyl Esters -60BP providing Docosahexonic acid 90mg, Mecobolamin acid 60mg, Pyrodoxine 3mg, Folic Acid 1.5 mg, Vitamin E 25IU , Vitamin C 100g, Zinc Sulphate 15mg, Sodium selenite 60mg as under:-

Computation of Retail Price per Capsule	Source/Method	Omegaful Capsule
Composition - Omega-3 Acid Ethyl Esters 60 BP providing Elcosapentaenoic Acid – 90mg, Docosahexaenoic Acid- 60mg, Mecobalamine- 500mcg, Pyridoxine Hydrochloride IP – 3mg, Folic Acid- 1.5mg, Vitamin-E- 25IU, Vitamin- C- 100mg, and Zinc Sulphate IP eq. to Elemental Zinc 15mg sodium selenite pentahydrate BP eq. to Elemental Selenium – 60mcg		
a. Notified price of formulation specified in the notification for 10 capsule	S.O. No. 2042(E) dated 30.11.2007 (DPCO, 1995)	11.32

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b. Total ceiling price Adjustment for 10 capsule	S.O. No. 2458(E) dated 24.09.2009 (Adjustment Factors)	(-) 2.47
Worked out Retail Price for 10 capsule under DPCO 1995		8.85
Annual increase of 10% as specified under para 10 of DPCO 2013 for 6 years. (i.e 6 times)		$8.85 \times (1.1)^6$
Worked out Retail price for 10 capsule under DPCO 2013		15.59
Worked out Retail price per capsule under DPCO 2013	1 capsule	1.56
Company Claimed Price	1 capsule	10.00
Recommended price	1 capsule	1.56

2. After deliberations, the Committee decided to recommend the worked out retail price, being lower, at Rs. 1.56 per capsule.

**Agenda No. 4 Sioneuron F Tablet containing Multivitamins of M/s Albert David Ltd. (Application received on 14.7.2016).**

1. The worked out retail prices for Sioneuron F Tablet containing Multivitamins Thiamine 10mg, Pyridoxine 3mg, Cynaocobalamin 15mcg, Nicotinamide 100 mg, Riboflovin 10mg, Vitamin 150 mg and Folic Acid 1500 mcgs is as under:-

Computation of Retail Price per Tablet	Source/Method	Sioneuron F Tablet
Composition - Each film coated tablet contains: Thiamine Mononitrate IP 10mg, Pyridoxine Hydrochloride IP 3mg, Cyanocobalamin IP 15mcg, Nicotinamide IP 100mg, Calcium Pantothenate IP 50mg, Riboflavin IP 10mg, Vitamin C IP 150mg, Folic Acid IP 1500mcg		
a. Notified price of formulation specified in the notification for 10 tablet	S.O. No. 2458(E) dated 24.09.2009 (DPCO'1995)	7.62
b. Total ceiling price Adjustment for 10 tablet	S.O. No. 2458(E) dated 24.09.2009 (DPCO'1995)	1.14
Worked out Retail Price for 10 tablet under DPCO 1995		8.76
Annual increase of 10% as specified under para 10 of DPCO 2013 for 6 years.(i.e 6 times)		$8.76 \times (1.1)^6$
Worked out Retail price for 10 tablet under DPCO 2013	10 tablets	15.52
Worked out Retail price per tablet under DPCO 2013	1 tablet	1.55

Company Claimed Price	1 tablet	5.50
Recommended price	1 tablet	1.55

2. After deliberations, the Committee decided to recommend the worked out retail price, being lower, at Rs. 1.55 per tablet.

**Agenda No. 5 Vaccine Easy four-TT PFS containing Diphteria Toxid 20LF 30 IU, Tetanus Toxid 7.5LF 60IU, Inactivated w-B pertussis bulk 12IOU 4IU, Hib PRP conjugated with carrier protein Tetanus Toxid 10 µg etc fully Liquid of M/s Panacea Biotech Ltd. (Application received on 22.7.2016)**

The Committee deliberated the issue in details. The Committee also observed that the previous Committee decided that the retail price of the subject formulation may be considered but not exceeding the same of competitors' products like QUARDRVOX and COMVAC 3+ BioHib available in the market and may be fixed as per para 5 of the DPCO, 2013 without differentiating between in pre-mixing/two-vials and single vial as there is no significant therapeutic advantage in single vial over pre-mixing/two vials and accordingly the draft worked out retail price comes to Rs. 210.31 based on QUARDRVOX data only as the other product's (i.e. COMVAC 3+ BioHib) data is not available in PharmaTrac.

The Multidisciplinary Committee deliberated the matter in detail. It noted that Easy-Four PFS product was a ready-to-inject liquid preparation, which was technically convenient at the point of delivery to infants, covering the issues, like of loss of sterilization (while multiple vials containing powders are being reconstituted and mixed by the nursing staff), and possibility of inexact dosing (that can crop in while preparing mixture from multiple vials post reconstitution). PFS is a big technological advantage from that point of view, and the committee noted that company must have done good formulation development work for preparing a stable liquid ready-to-inject product of multiple vaccines, which otherwise tend to be unstable. Therefore, considering various technical aspects involved in the product processing, stabilization of the liquid product, requirement of new manufacturing line for PFS, etc., it agreed to recommended the asked retail price per 0.5mg PFS, but only if the company was able to justify the cost, for which the company representatives be invited in the next meeting. The committee noted that a letter was sent by NPPA to company in May 2017 to justify the cost even of their old product, but the reply is still awaited. So it would be better if company representatives come and explain the reason of high cost of their products versus other products in the market.

**Agenda No. 6& 7 Cyblex MV 40.2 each tablet contain Metformin HCL 500mg + Gliclazide 40mg + Voglibose 0.2mg and Cyblex MV 40.3 each tablet contain Metformin HCL 500mg + Gliclazide 40mg + Voglibose 0.3mg by M/s Eris Lifesciences Ltd. (WPA case received on 14.12.2016)**

The Committee deliberated the matter in details. The Committee observed that the subject formulations are sub-judice due to its being irrational FDC. Accordingly, the Committee decided to defer the cases till the decision is obtained from CDSCO.

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**Agenda No. 8 Manufactured by M/s Mylan Laboratories Limited and Marketed by M/s Mylan Pharmaceutical Pvt. Ltd. AVONZA Tablet Each tablet contains: Tenofovir Disoproxil Fumarate 300mg, Lamivudine 300mg, Efavirenz 400mg.**

1. The worked out retail prices for AVONZA Tablet containing Tenofovir Disoproxil Fumarate 300mg, Lamivudine 300mg and Efavirenz 400mg is worked out as under:-

Computation of Retail Price per Tablet	Source/Method	AVONZA Tablet
Composition - Tenofovir Disoproxil Fumarate 300mg, Lamivudine 300mg and Efavirenz 400mg		
a. Tenofovir Disoproxil Fumarate 300mg, Lamivudine 300mg and Efavirenz 600mg	Ceiling Price	93.52
b. Less Efavirenz 200mg	Ceiling Price	20.57
Worked out Retail Price	1 tablet	72.95
Company Claimed Price	1 tablet	60.00
Recommended price	1 tablet	60.00

2. The Committee noted that only efavirenz bulk drug price of 200 mg was needed to be subtracted instead of ceiling price (CP) of full formulation of Efavirenz 200 mg. But as claimed retail price is lower at Rs. 60.00 per tablet, the Committee decided to recommend the same. However, since price worked out by NPPA is higher than the one claimed, the committee felt that exact reasons need to be explored, as the same situation has been with other cases also.

**Agenda No. 9 & 10 Volini Maxx Gel 20GM contains: Diclofenac Diethylamine BP 2.32%w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w Menthol IP 5% w/w Manufactured and marketed by M/s Sun Pharmaceuticals Industries Pvt. Ltd.**

In the absence of proper Pharamaeconomic lead, the Committee deferred the matter for the next meeting.

**Agenda No. 16. HEPBEST Tablet Contains: Tenofovir Alafenamide Fumarate 25mg Tablet Manufactured by M/s Mylan Laboratories Pvt. Ltd. and Marketed by M/s Mylan Pharmaceuticals Pvt. Ltd**

The Committee deliberated on the matter and directed NPPA office to request the company to furnish data/information regarding:

- Therapeutic equivalence/ differentiation between the company's product and other available product
- Technical details of the product
- The manufacturing process involved in the product

**Agenda No. 18. 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.**

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The Committee deliberated on the matter and directed NPPA office to request the company to furnish data/information regarding:

- a. Therapeutic equivalence/differentiation between the company's product and other available product
- b. Technical details of the product
- c. The manufacturing process involved in the product

**Agenda No. 19. Each PFS injection for subcutaneous use containing: Recombinant Human Chorionic Gonaotropin 6500IU manufactured & marketed by M/s Bharat Serum and Vaccines Ltd**

The Committee deliberated the matter in details. The Committee observed that the Human Chorionic Gonaotropin injection with strength of 1000IU and 5000IU are scheduled formulations and the applicable ceiling prices as on July 2017 are Rs. 192.84 per pack and Rs. 378.71 per pack, respectively. The Committee decided to recommend the retail price of Recombinant Human Chorionic Gonaotropin PFS injection 6500IU by extending the ceiling price of Human Chorionic Gonaotropin injection 5000IU by adopting method of extrapolation. Accordingly, the cost of the retail price of Recombinant Human Chorionic Gonadotropin injection 6500IU was calculated as Rs. 492.32 per pack. But the committee felt that there was need to confirm whether Human Chorionic Gonaotropin injection with strength of 1000IU and 5000IU, which are scheduled formulations, were marketed in vial or as prefilled syringes (PFS), as the cost of PFS is different to any company, against product manufacturing in simple vials.

**Agenda No. 3, 11,12,13,14,15 & 17**

The Committee observed that the retail price in all these cases were calculated by NPPA by taking summation of ceiling price of individual dosage form(s), instead of drug substances that form part of the fixed dose combinations (FDCs). This results in duplication of all types of costs (excipients, packaging, testing, shipping and distribution, etc.), except for the cost of drug substances. It is perhaps the precise reason that NPPA calculations have higher determined costs in some cases, opposite to lower cost claims by the companies (Agenda no. 8, for example). Therefore, the price of the FDC formulations needs to be worked out after subtracting all kind of cost duplications, other than cost of drug actives. NPPA officials were requested by the committee to think over all possibilities of solving this problem, and report in the next meeting.

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

**Agenda No 1. Review order no.31015/08/2017-Pricing dated 30.10.2017 Review order in respect of Timolol Drops 0.5% Eye Drops filed by M/s Sun Pharma Laboratories Ltd.**

The Committee deliberated on the additional documents submitted by the company. Further, the company also gave demonstration about the product. The representatives of the company were not able to provide good justification on innovation. Accordingly, the

Committee directed them to furnish additional technical documents/ literature of their products w.r.t. novelty, potency, PK/PD and therapeutic benefit (in particular, data submitted by them to CDSCO for approval of products) within fifteen days.

**Agenda No 2. Review order no.31015/25/2017-Pricing dated 30.10.2017 Review order in respect of Methylprednisolone 40mg/ml Injection filed by M/s Cadila Healthcare Ltd.**

The Committee deliberated on the additional documents submitted by the company. The Committee observed that there is no significant therapeutic advantage in the two form and the therapeutic end results is same in both the form. Accordingly, the Committee recommended that no separate price of Methylprednisolone Injection as suspension for injection and Methylprednisolone Sodium Succinate powder for injection may be given.

**Agenda No 3. Review order no. 31015/61/2017-Pricing dated 11.01.2018 Review order in respect of Sodium Valproate Tablet 200 mg filed by M/s Sun Pharmaceutical Industries Ltd.**

The Committee observed that the matter was already deliberated and recommended by the Committee in its 1<sup>st</sup> meeting. However, the Authority in its 56<sup>th</sup> meeting dated 23.04.2018, decided to refer back the cases to the Committee again for reconsideration after co-opting a clinical pharmacologist and therapeutical expert as a member. Accordingly, a pharmacologist, Dr. C. D. Tripathi, Head of Pharmacology, VMMC & Safdarjung Hospital, was co-opted as member in the Committee. Accordingly, the Committee deliberated on the matter. Further, the company also gave demonstration about the product. The representatives of the company were not able to provide good justification on innovation. Accordingly, the Committee directed them to furnish additional technical documents/literature of their products w.r.t. novelty, potency, PK/PD and therapeutic benefit (in particular, data submitted by them to CDSCO for approval of products) within fifteen days.

**Agenda No. 4. Review order no.31015/14/2017-Pricing dated 11.01.2018 Review order in respect of Omeprazole 20mg tablets filed by M/s Cadila Healthcare Ltd.**

The Committee observed that the matter was already deliberated and recommended by the Committee in its 1<sup>st</sup> meeting. However, the Authority in its 56<sup>th</sup> meeting dated 23.04.2018, decided to refer back the cases to the Committee again for reconsideration after co-opting a clinical pharmacologist and therapeutical expert as a member. Accordingly, a pharmacologist, Dr. C. D. Tripathi, Head of Pharmacology, VMMC & Safdarjung Hospital, was co-opted as member in the Committee. The Committee again deliberated on the matter and went with the decision taken in the 1<sup>st</sup> meeting and recommended that the formulation Omeprazole Tablet includes the Omeprazole magnesium tablet of specified strength. Accordingly, the claim of the applicant cannot be considered.

**Agenda No. 5. Review order no.31015/86/2017-Pricing dated 26.02.2018 Review order in respect of Ciprofloxacin 500 mg tablets filed by M/s Sun Pharmaceutical Industries Ltd.**

The Committee deliberated on the additional documents submitted by the company. Further, the company also gave demonstration about the product. The representatives of the company were not able to provide good justification on innovation. Accordingly, the Committee directed them to furnish additional technical documents/literature of their products w.r.t. novelty, potency, PK/PD and therapeutic benefit (in particular, data submitted by them to CDSCO for approval of products) within fifteen days.

**Agenda No. 6. 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 was deferred.

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



(Prasenjit Das)  
Asstt Director (Pricing)

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All members of the Committee