F.No. 12(7)/2017/DP/NPPA/Div.II

National Pharmaceutical Pricing Authority

Subject: Minutes of the 3rd meeting of Multidisciplinary Committee of Experts held on 13.06.2018 at 11:00 AM in NPPA

The 3rd meeting of the "Multidisciplinary Committee of Experts" was held on 13.06.2018 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. K. Bangarurajan, Jt. Drugs Controller, CDSCO
3. Dr. C. D. Tripathi, Director-Professor, Deptt of Pharmacology, VMMC & Safdarjung Hospital
4. Dr. Gaurav Pratap Singh, Sr. Scientific Officer, Indian Pharmacopoeia Commission
5. Sh. Baljit Singh, Assistant Director (Pricing), NPPA
6. Sh. Prasenjit Das, Assistant Director (Pricing), NPPA

The members of the Committee 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. 2 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)

M/s Panacea Biotech Ltd gave a technical presentation before the Committee. The Committee deliberated on the technical presentation given by the company and directed the company to furnish detailed cost justification of price of Rs. 530.00 at which the company was earlier selling/ marketing the product and also the detailed justification regarding claimed retail price of Rs. 620 per PFS or vial **within a week period.**

Agenda No. 3 & 4 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)

As the matter of rationality is still in the Hon'ble High Court, the Committee decided to defer the cases till the communication is received from CDSCO.

Agenda 5 & 6 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.

The Committee deliberated on the issue and observed that NPPA has already fixed the retail price of spray having the same formulation for M/s Sun Pharmaceutical Industries Ltd. Accordingly, the Committee recommended to collect the market data prices of brand having gel as well as spray form of other formulations to enable the committee to recommend the price of Volini Gel.

Agenda 12 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.

M/s Mylan Pharmaceuticals Pvt Ltd gave a technical presentation before the Committee. The Committee deliberated on the matter and directed the company to furnish the following details:

a. The licensing agreement for the manufacture of the formulation.

b. Price justification of claimed retail price.

Since M/s Cadila Healthcare Ltd/ M/s Hetero Pharmaceuticals Ltd have submitted application to fix the retail price of the same formulation, they were also called to give presentation before the Committee. M/s Cadila Healthcare Ltd/ M/s Hetero Pharmaceuticals Ltd gave technical presentation before the Committee. The Committee directed the company to furnish the following documents:

a. The licensing agreement for the manufacture of the formulation or **evidence of patents, if any, filed by the company, in case the process is different from innovator and the product is not in-licensed from Gilead.**

b. Price justification of claimed retail price.

The committee noted with concern that all products of Tenofovir Alafenamide Fumarate 25mg Tablets are priced uniformly in the market in India. It decided to discuss whole case in the next meeting, after getting replies from the companies.

Agenda 14 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.

M/s Bharat Biotech international Ltd gave technical presentation before the Committee. The Committee deliberated on the issue and directed the company to furnish detailed justification for the price claimed by them within a week period.

Agenda No. 18. Each PFS injection for subcutaneous use containing: Recombinant Human Chorionic Gonaotropin 6500IU manufactured & marketed by M/s Bharat Serum and Vaccines Ltd

Deferred for want of the information from the manufacturer.

Agenda No. 1, 7-11,13 & 15.

1	Brinzolamide 1% and Timolol 0.5% eye drops in 5ml vial of Ajanta Pharma Ltd. (Application received on 30.5.2016)
7	TRIOLSAR 20 Tablet: Each film coated tablet contains Olmesartan Medoxomil 20mg, Chlorthalidone IP 6.25mg, Amlodipine Besylate,IP eq. to Amlodipine 5mg tablets Manufactured by M/s GKM New Pharma. and Marketed by M/s Unichem Laboratories Limited.
8	TRIOLSAR 40 Tablet Each film coated tablet contains: Olmesartan Medoxomil 40mg, Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets Manufactured by M/s GKM New Pharma. and Marketed by M/s Unichem Laboratories Limited
9	TRILOSAR 6.25 Tablets Each film coated tablet contains: Losartan Potassium IP 50mg, Chlorthalidone IP 6.25mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets Manufactured by M/s GKM New Pharma. and Marketed by M/s Unichem Laboratories Limited
10	TRILOSAR 12.50 Tablets Each film coated tablet contains: Losartan Potassium IP 50mg, Chlorthalidone IP 12.503mg, Amlodipine Besylate IP eq. to Amlodipine 5mg tablets Manufactured by M/s GKM New Pharma. and Marketed by M/s Unichem Laboratories Limited
11	Manufactured and Marketed by M/s Apex Laboratories Pvt. Ltd contains: Sodium Fusidate IP eq. to Fusudic Acid 2%w/w, Halobetasol Propionate USP 0.05%w/w
13	Each film coated tablet contains: Darunavir Ethanolate eq. to Darunavir 600mg and Ritonavir IP 100mg tablet Manufactured & Marketed By M/s Emcure Pharmaceuticals Limited
15	Each film coated tablet contains: Each tablet contains: Tenofovir Disoproxil Fumarate 300mg, Lamivudine 300mg and Dolutegavir 50mg tablet Manufactured & Marketed By M/s Emcure Pharmaceuticals Limited

The Committee directed the NPPA to devise a price mechanism for solving pricing issue related to combination of two medicines and report in the next meeting for recommending suitable price of the combination drugs under pharmacoeconomics.

B. Agenda relating to Para 11(3&4) of DPCO 2013 and any other matter

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.

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Agenda No 2. 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 Industrles Ltd.

One of the views emerged in the meeting to give separate ceiling prices for the OD formulation be segregated and calculated separately while there was another view that such formulations should be considered as included for pricing purpose as the technology of the OD(once a day) is available since long. The Committee also noted the direction in the Review order to refer the matter to the expert committee and observed that, para 11(3) and 11(4) was inserted in DPCO 2013 vide notification dated 22.3.2016 with the objective to recommend fixing of separate ceiling price of scheduled formulations or retail price of a new drug considering the type of packaging or pack size or dosage compliance or content for the

a. Injection,
b. Inhalation,
c. Any other medicine for which dosage form or strength or both are not specified in the Schedule-I of the Drugs (Prices Control) Order, 2013

However, the formulations under consideration are eye drops / tablets with specified dosages form and strength and are not covered in the para 11(3) of the DPCO 2013. Hence, the para 11(3) is not applicable to such formulations.

In view of the above, it is decided to reconsider the matter after referring back to DoP.

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 1st meeting. However, the Authority in its 56th meeting dated 23.04.2018, decided to refer back the cases to the Committee again for reconsideration after co-opting a clinical pharmacologist and therapeutic 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 Committee deliberated the issue in details and noted that "Encorate Chrono 200 mg tablet" contains combination of sodium valproate 133.33 mg and valporic acid 58 mg tablet corresponds to sodium valproate 200 mg tablet formulation. This is also mentioned in the label of the product of the applicant. The Committee also noticed that the product of Sanofi India namely "Valparin 200 mg tablet 10" having market share of more than 65% is also the combination of sodium valproate 133.33 mg and valporic acid 58 mg tablet corresponding to sodium valproate 200 mg tablet formulation. Accordingly, the Committee found that note (i) "The formulation of Sodium Valproate includes combination of Sodium Vaproate and Valporic Acid both together corresponding to Sodium Valproate of the stated strength" of the SO.1569(E) dated 15.5.2017 was rightly stated and is in order.

Agenda No. 4. Review order in respect of Ringer Lactate Injection filed by Aculife Healthcare Private Ltd, Albert David Ltd, B.Braun Medical (India) Pvt. Ltd, Fresenius Kabi India Private Ltd and Otsuka Pharmaceutical India Private Limited

The parties could not be invited due to presentation by other companies in this meeting. Hence the agenda was deferred.

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