

मिसिल स.- 8(57)/2018/डी.पी/एनपीपीए-डीवी-II
F. No. 8(57)/2018/DP/NPPA-Div. II

कार्यवाहीस. : 189/57/2018/F
Proceeding No : 189/57/2018/F

Minutes of the 189th (overall) and 57th meeting of the Authority under DPCO, 2013 held on 08.06.2018 at 11:30 A.M

I. The 189th overall meeting of the Authority, which is the 57th meeting under the DPCO, 2013, was held on 8th June, 2018 at 11:00 AM under the Chairmanship of Dr. Rakesh Kumar Vats, Chairman, NPPA. The following members of the NPPA were present:

- (i) Ms. Ritu Dhillon, Member Secretary
- (ii) Dr. S. Eswara Reddy, DCG(I)
- (iii) Shri Arun Kumar, Adviser, Deptt. of Economic Affairs, Ministry of Finance.
- (iv) Shri A.K.Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare

1.1 The following officers of NPPA also attended the meeting and assisted the Authority in its deliberations:

- i. Shri Kalyan Nag, Adviser (Cost)
- ii. Shri Baljit Singh, Asstt. Director (Pricing)
- iii. Shri Prasenjit Das, Asstt. Director (Pricing)

1.2 Chairman, NPPA welcomed all the members present in the meeting.

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 56th Meeting held on 23.04.2018.

1.1 The Authority confirmed the minutes of the 188th (overall) and the 56th Meeting under DPCO 2013 held on 23.04.2018.

2. Agenda item no. 2 - Action Taken Report

2.1 Noted.

3. Agenda item no. 3 - Status of New Drug application

3.1 The Authority noted the pending new drug applications and directed that a reminder be sent in respect of cases referred to DCGI.

4. **Agenda item no. 4 – New Drug application**

4.1. The Authority discussed the following cases of retail price fixation of new drugs in Agenda no. 4(i) to 4(xx) [Agenda no 4(xix) and 4(xx) submitted as additional items] falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices of 20(twenty) cases under para 5 of the DPCO 2013. The following retail prices were approved:

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Methylcobalamin + Alpha Lipoic Acid + Pyridoxine Hydrochloride + Folic Acid + Vitamin D3 1000IU Tablet	Each film coated tablet contains: Methylcobalamin IP 1500mcg, Alpha Lipoic Acid USP 100mg, Pyridoxine Hydrochloride IP 3mg, Folic Acid IP 1.5mg Vitamin D3 1000IU	1 Tablet	M/s Sozin Flora Pharma LLP / M/s Zydus Healthcare Ltd.	10.31
2.	Methylcobalamin + Alpha Lipoic Acid + Pyridoxine Hydrochloride + Folic Acid + Vitamin D3 1000IU Tablet	Each film coated tablet contains: Methylcobalamin IP 1500mcg, Alpha Lipoic Acid USP 100mg, Pyridoxine Hydrochloride IP 3mg, Folic Acid IP 1.5mg Vitamin D3 1000IU	1 Tablet	M/s Mascot Health Series Pvt. Ltd / M/s Zydus Healthcare Ltd.	10.31
3.	Cefixime + Cloxacillin + Lactic Acid Tablet (ZIFI LBX +200)	Each film coated tablet contains: Cefixime IP as Trihydrate eq. to Anhydrous Cefixime 200mg, Cloxacillin Sodium IP eq. to Cloxacillin 500mg (in Extended Release form), Lactic Acid Bacillus 90 Million Spores	1 Tablet	M/s Malik Lifesciences Pvt. Ltd. / M/s FDC Limited	11.48
4.	Omeprazole + Domperidone Capsule (OZSON-DSR)	Each hard gelatin capsule contains: Omeprazole 20mg (As enteric coated pellets), Domperidone (As Sustained Release Pallets) 30mg	1 Capsule	M/s Unison Pharmaceuticals Pvt. Ltd.	2.68
5.	Clotrimazole + Beclomethasone Cream (CZSON-B)	Cream contains: Clotrimazole 1.0% w/w + Beclomethasone Dipropionate 0.025% w/w	1 GM	M/s Tuton Pharmaceuticals / M/s Unison Pharmaceuticals Pvt. Ltd.	2.15
6.	Clotrimazole + Beclomethasone + Neomycin Cream (CZSON-NB)	Cream contains: Clotrimazole 1.0% w/w + Beclomethasone Dipropionate 0.025% w/w, Neomycin Sulphate eq. to Neomycin Base 0.5w/w Cream	1 GM	M/s Tuton Pharmaceuticals / M/s Unison Pharmaceuticals Pvt. Ltd.	1.93
7.	Linezolid Suspension (ZIFI TURBO KID)	Each 5ml of the reconstituted suspension contains: Linezolid IP 100mg in a flavored base	1 ML	M/s Theon Pharmaceuticals Ltd. / M/s FDC Limited	2.77

8.	Linezolid Suspension (LIZOFLY)	Each 5ml of the reconstituted suspension contains: Linezolid IP 100mg in a flavored base	1 ML	M/s Sava Healthcare Ltd. / M/s Brinton Pharmaceuticals Ltd.	2.77
9.	Rosuvastatin + Clopidogrel Tablet (ROSUVAS CV 10)	Each film coated tablet contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg, Clopidogrel Bisulfate IP eq. to Clopidogrel 75mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Sun Pharmaceutical Industries Ltd.	10.96
10.	Olmesartan + Amlodipine + Amlodipine Tablet (Triolmezest CH 20)	Each film coated tablet contains: Olmesartan IP 20 mg Amlodipine Besylate IP eq. to Amlodipine 5 mg Chlorthalidone IP - 12.5 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Sun Pharma Laboratories Ltd.	8.78
11.	Olmesartan + Amlodipine + Amlodipine Tablet (Triolmezest CH 40)	Each film coated tablet contains: Olmesartan IP 40 mg Amlodipine Besylate IP eq. to Amlodipine 5 mg Chlorthalidone IP - 12.5 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Sun Pharma Laboratories Ltd.	15.53
12.	Telmisartan + Amlodipine + Chlorthalidone Tablet (Telvas 3D CT 40/6.25)	Each film coated tablet contains: Telmisartan 40mg, Amlodipine 5mg & Chlorthalidone 6.25mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	8.63
13.	Telmisartan + Amlodipine + Chlorthalidone Tablet (Telvas 3D CT 80/6.25)	Each film coated tablet contains: Telmisartan 80mg, Amlodipine 5mg & Chlorthalidone 6.25mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	14.40
14.	Norethisterone Tablet	Each film coated controlled release table contains: Norethisterone Acetate BP 10mg Tablet	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Obsurge Biotech Limited	12.89
15.	Alpha Lipoic + Vitamin D3 + Pyridoxine + Mecobalamin + Folic Acid + Biotin Tablet (Nervijen D3)	Each coated tablet contains: Alpha Lipoic Acid 200mg Vitamin D3 1000 IU Pyridoxine HCl 3mg Mecobalamin 1500mcg Folic Acid 1.5mg Biotin 200mcg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Jenburkt Pharmaceuticals Ltd.	3.06
16.	Omega-3 (Eicosapentaenoic + Docosahexaenoic) + Mecobalamine + Pyridoxine + Folic Acid + Vitamin E + Vitamin C + Zinc Sulphate + Sodium selenite Capsule (Omegaful)	Each soft gelatine Capsule contains: Omega-3 Acid Ethyl Esters 60 BP providing Eicosapentaenoic Acid 90mg, Docosahexaenoic Acid 60mg, Mecobalamin- 500mcg, Pyridoxine Hydrochloride IP 3mg, Folic Acid 1.5mg, Vitamin E 25IU, Vitamin C 100mg, and Zinc Sulphate IP eq. to Elemental Zinc 15mg	1 Capsule	M/s Mankind Pharma Ltd. / M/s Magnet Labs Pvt. Ltd.	1.56

		Sodium selenite pentahydrate BP eq. to Elemental Selenium 60mcg			
17.	Thiamine Mononitrate + Pyridoxine Hydrochloride + Cyanocobalamin + Nicotinamide + Calcium Pantothenate + Riboflavin + Vitamin C + Folic Acid Tablet (Sioneuron F)	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	1 Tablet	M/s Albert David Limited	1.55
18.	Tenofovir Disoproxil Fumarate + Lamivudine + Efavirenz Tablet (AVONZA)	Each tablet contains: Tenofovir Disoproxil Fumarate 300mg, Lamivudine 300mg, Efavirenz 400mg	1 Tablet	M/s Mylan Laboratories Limited / M/s Mylan Pharmaceutical Pvt. Ltd.	60.00
19.	Diclofenac + Methyl Salicylate + Menthol (Volini Maxx Spray in 25gm Pack)	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	25 GM	M/Sun Pharmaceuticals Industries Ltd.	156.25
20	Diclofenac + Methyl Salicylate + Menthol (Volini Maxx Spray in 55gm Pack)	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	55 GM	M/Sun Pharmaceuticals Industries Ltd.	296.87

4.2 The Authority noted that in agenda 4(xix & xx) M/s Sun Pharmaceuticals Industries Ltd has applied for the retail price of Volini Maxx spray in 25gm and 55 gm pack respectively. The Authority observed that the retail price of Volini Maxx spray with pack size of 15 gm, 30gm, 40gm and 60gm was fixed in 56th meeting held on 23.04.2018. Accordingly, the Authority decided to fix the retail price of 25gm and 55 gm by extending the retail price of volini maxx spary given earlier vide SO. 1766(E) dated 26.04.2018 in the following ways:

a. 25 gm pack: The 25 gm pack may be fixed by applying unitary method on the retail price fixed for 30 gm pack.

Accordingly, the proposed retail price comes to Rs. 156.25 for 25 gm pack.

b. 55 gm pack: The 55 gm pack may be fixed on the basis of price fixed for 30 gm by applying the following formula:

$$P(s)=P* \times [1+0.7 \times \{(s-30)/30\}]$$

Where, P(s)= price for pack sizes

P* = ceiling price for reference pack size (30 gm)

s= pack size for which price is to be fixed (i.e. 55 gm)

Accordingly, the proposed retail price comes to Rs. 296.87 for 55 gm pack.

5. Agenda item no. 5 - Implementation of review orders

5.1 Agenda item no. 5(i) Directions by DoP with respect to review applications filed by various pharmaceuticals companies against fixation of ceiling price of scheduled formulations under Para 19 of DPCO, 2013 on the basis of procurement prices.

5.1.1. The Authority deliberated upon the issue in detail. The Authority decided to re-fix the ceiling price on the basis of data provided by the manufacturers with respect to the formulations where directions were received from DoP.

5.1.2. The Authority also decided to issue corrigendum in respect of Anti-Tetanus Immunoglobulin 250IU by specifying the strength in the respective column in the notification.

5.1.3. The Authority also decided that where ceiling price of scheduled formulations were earlier fixed under paragraph 19 of DPCO, 2013 based on the procurement prices of the government agencies and the manufacturer has given representation citing unviability, the representation shall be considered by the NPPA without waiting for Review order from the DoP.

5.2 Agenda item no. 5(ii) Review order no. 31015/14/2016-Pricing dated 11.01.2018 in respect of M/s Zydus Healthcare Ltd for Omeprazole 20 mg tablet.

5.2.1 The Authority deliberated upon the recommendations made by the multidisciplinary Committee of Experts on 25.5.2018, on the review order. The Authority rejected the contention of the review applicant and decided to close the review order no. (31015/14/2016-Pricing dated 11.01.2018) in respect of M/s Zydus Healthcare Ltd for Omeprazole 20 mg tablet without any change in the ceiling price.

5.3 Agenda item no. 5(iii) Review order no. 31015/25/2017-Pricing dated 30.10.2017 in respect of M/s Cadila Healthcare Ltd for Methylprednisolone 40mg/ml injection.

5.3.1 The Authority deliberated upon the recommendations made by the multidisciplinary Committee of Experts on 25.5.2018 on the review order. The Authority rejected the contention of the review applicant and decided to close the review order no. (31015/25/2017-Pricing dated 30.10.2017) in respect of M/s Cadila Healthcare Ltd for Methylprednisolone 40mg/ml injection without any change in the ceiling price.

5.4 Agenda item no. 5(iv) Review orders relating retail price fixed by giving price extension in respect of a medicine for which the price was fixed earlier.



5.4.1 The Authority in its 51st meeting dated 15.12.2017 took a principle decision that *"With a view to rationalize the price of new drugs, the Authority decided that wherever, the application has been received by NPPA for any new drug for which NPPA has already notified the price, the same price would be extended to subsequent applicants also."*

NPPA has fixed more than 100 retail prices of new drugs, as per the above policy, in the months of Dec-2017, Jan 2018 and Feb 2018. Subsequent to this, some of the companies filed review petitions with DoP. The grievances of the companies were examined by the DoP. NPPA received various review orders from the DoP in the months of May 2018, directing NPPA to re-fix the retail prices of new drug strictly as per provision of para 5(1) read with para 9(4) of DPCO, 2013.

Keeping in view the provision of para 31 of the DPCO 2013, the authority decided to re-fix the retail price of new drugs strictly as per provision of para 5(1) read with para 9(4) of DPCO, 2013, in respect of these case where review orders are given by DoP.

5.4.2 The Authority also noted additional directions given in the review orders referred to above *".....to take similar action in all similar cases within a period of one month from the date of issue of the order"*. The Authority, after careful examination of the issues involved, decided to issue a letter to DoP that in cases, where the retail price was earlier fixed by the NPPA on the basis of the policy stated in the para 5.4.1 refixation would be done only in those cases where there is a specific review order.

5.4.3 The Authority deliberated upon the directions given in the various review orders issued by DoP in respect of 'new drug'. Accordingly, the Authority decided that, henceforth, the retail price of new drugs would be fixed based on

(a) the retail price calculated strictly as per the para 5 of DPCO 2013, or

(b) the retail price claimed by the company;

whichever is less

The authority also decided that the retail price notified for other manufacturers shall not be considered in the computation.

5.5 Agenda item no. 5(v) Review order 31015/33/2016-Pl.I dated 19.9.2016 in respect of M/s Fresenius Kabi India Pvt Ltd against ceiling price fixation of Paclitaxel Injection.

5.5.1 The Authority observed that the review order had already been closed by the Authority. However, as a letter had been received from DoP, the Authority decided to write to the core committee of NLEM for their views on the matter as suggested by DoP.

5.6 Agenda item no. 5(vi) Review order no 31015/30/2016-PII dated 14.9.2016 and no 31015/82/2016-PII dated 5.4.2017 in respect of Oral Rehydration Salts

5.6.1 The authority noted the clarification given by the Ministry of Health and Family welfare in respect of 'Oral Rehydration Salts' and decided to accept the recommendations of excluding the sports drinks/ENERZAL for working out the ceiling price of the 'Oral Rehydration Salts'. Accordingly, the authority decided to revise the ceiling price to Rs. 0.83 per gram from the existing Rs. 0.74 per gram.

5.7 Agenda item no. 5(vii) Review order no 31015/33/2017-pricing dated 24.8.2017 of M/s Cadila Healthcare Ltd in respect of Co-trimoxazole [Sulfamethoxazole (A) and Trimethoprim(B)] Tablet 800mg(A) +160mg(B)

5.7.1 The authority deliberated and reconsidered the review order in the light of the further documents received from the applicant and decided to revise the ceiling price of Co-trimoxazole [Sulfamethoxazole (A) and Trimethoprim(B)] Tablet 800mg(A) +160mg(B) to Rs. 1.27 per tablet from the existing ceiling price of Rs. 0.99 per Tablet.

6 Agenda item no. 6 Status of overcharging cases

6.1 Noted

7. Agenda item no. 7 Minutes of the 2nd meeting of Multidisciplinary Committee of Experts held on 25.05.2018.

7.1 Noted.

8. Agenda item no. 8 Registration of various products as "Cosmetics" instead of "Drugs" under Drugs and Cosmetics Act, 1940

8.1 DCGI will submit comments.

The meeting ended with a vote of thanks to the Chair.


(Ritu Dhillon)
Member Secretary

