

मिसिल स.- 8(66)/2019/डी.पी/एनपीपीए-डीवी-॥

F. No. 8(66)/2019/DP/NPPA-Div. II

कार्यवाहीस. : 198/66/2019/F

Proceeding No : 198/66/2019/F

Minutes of the 198th (overall) and 66th meeting of the Authority under DPCO, 2013 held on 24.04.2019 at 11:00 AM

The 198th meeting of the Authority (overall), which is the 66th meeting under the DPCO, 2013, was held on the 24th of April, 2019 at 11:00 AM under the Chairmanship of Ms. Shubhra Singh, Chairman, NPPA. The following members of the NPPA were present:

- (i) Ms. Ritu Dhillon, Member Secretary
- (ii) Shri Arun Kumar, Advisor, Dept of Economic Affairs, Ministry of Finance
- (iii) Shri B. Bandyopadhyay, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Shri A.K.Pradhan, Deputy Drug Controller, Deptt. of Health & Family Welfare was present as representative of DCGI.

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

- (i) Shri Kalyan Nag, Advisor
- (ii) Shri Amarpal Singh Sawhney, Director (Pricing)
- (iii) Shri Arun Kumar Diwan, Dy. Director (M&E)
- (iv) Shri Prasenjit Das, Asstt. Director (Pricing)
- (v) Shri Prakash Hemani, Asstt. Director (Pricing)

Chairman, NPPA welcomed all present in the meeting.

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 65th Meeting held on 27.03.2019.

1.1 Noted.

2. Agenda item no. 2 – Action Taken Report

2.1 Noted.

3. Agenda item no. 3 – Status of New Drug applications

3.1 The Authority noted the status of new drug applications.

3.2 Apart from 23 applications listed for consideration in the meeting, only 6 applications were under process, as received upto 31.03.2019. The Authority expressed satisfaction at the

pace of disposal. The application of M/s Bharat Biotech International Ltd is to be followed up with Ministry of Health & Family Welfare and be brought to the Authority in its next meeting.

4. Agenda item no. 4 – New Drug applications

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(xxiii) (total 23 Form I applications) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 20(twenty) cases [except three cases at sl no (xii), (xiv), (xv)] under para 5 and para 15 of the DPCO 2013, as detailed below:

A. Retail price fixed under para 5 of DPCO, 2013

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price excluding GST (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
(i)	Mesalazine Sachet	Each sachet contains: Mesalazine IP 2gm (As Coated Granules)	2gm Sachet	M/s Sun Pharma Laboratories Limited	86.78
(ii)	Mesalazine Sachet	Each sachet contains: Mesalazine IP 1gm (As Coated Granules)	1gm Sachet	M/s Sun Pharma Laboratories Limited	43.28
(iii)	Clotrimazole + Beclomethasone + Neomycin Cream	Cream contains: Clotrimazole 1.0% w/w Beclomethasone Dipropionate 0.025% w/w Neomycin Sulphate eq. to Neomycin Base 0.5% w/w	1 GM	M/s Helios Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	5.34
(iv)	Telmisartan + Cilnidipine + Chlorthalidone Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg, Cilnidipine 10mg, Chlorthalidone IP 6.25mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Cipla Limited	10.72
(v)	Telmisartan + Cilnidipine Tablet	Each film coated tablet contains: Telmisartan IP 40mg, Cilnidipine 10mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s Cipla Limited	7.66
(vi)	Paracetamol + Phenylephrine + Caffeine (Anhydrous) + Diphenhydramine Tablet	Each uncoated tablets contains: Paracetamol IP 500mg, Phenylephrine HCL IP 5mg, Caffeine (Anhydrous) IP 30mg, Diphenhydramine HCL IP 25mg,	1 Tablet	M/s Samson Laboratories Pvt. Ltd. / M/s Intas Pharmaceuticals Limited	2.80
(vii)	Methylcobalamin + Pyridoxine + Folic Acid Tablet	Each film coated tablet contains: Methylcobalamin (Extended Release) IP 1500mcg, Pyridoxine Hydrochloride IP 20mg,	1 Tablet	M/s Tirupati Medicare Ltd. / M/s Cipla Limited	15.00

		Folic Acid IP 5mg			
(viii)	Olmesartan Medoxomil + Amlodipine + Hydrochlorothiazide Tablet (Trisertain 20)	Each film coated tablet contains: Olmesartan Medoxomil IP 20mg, Amlodipine Besilate IP Amlodipine 5mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Dr. Reddy's Laboratories Limited	10.54
(ix)	Olmesartan Medoxomil + Amlodipine + Hydrochlorothiazide Tablet (Trisertain 40)	Each film coated tablet contains: Olmesartan Medoxomil IP 40mg, Amlodipine Besilate IP Amlodipine 5mg, Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Dr. Reddy's Laboratories Limited	14.56
(x)	Levetiracetam Tablet (Epictal)	Each film coated tablet contains: Levetiracetam IP 1000mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s IPCA Laboratories Limited	24.56
(xi)	Olmesartan Medoxomil + Amlodipine Tablet (Olsertain AM 40)	Each film coated tablet contains: Olmesartan Medoxomil IP 40mg, Amlodipine Besilate IP Amlodipine 5mg,	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Dr. Reddy's Laboratories Limited	14.45
(xii)	Voveran 1ml AQ Injection	Each ml contains: Diclofenac Sodium IP 75mg, Water for Injection	1 ML	M/s Nitin Life Sciences / M/s Novartis India Limited	Deferred in view of representation received from the company
(xiii)	Linezolid + Dextrose Injection	ZIFI TURBO 600 Injection 300ml Each 100ml contains: Linezolid IP 200mg Dextrose Anhydrous IP 5mg water for Injection q.s.	Per Pack	M/s Aishwarya Lifesciences / M/s FDC Limited	330.79
(xiv)	Diclofenac + Thiocolchicoside Capsule	Each hard Gelatin capsule contains: Diclofenac Sodium IP 50mg (As Enteric coated tablet) Thiocolchicoside 4mg	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Novartis India Limited	Deferred in view of representation received from the company
(xv)	Diclofenac + Thiocolchicoside Capsule	Each Hard Gelatin capsule contains: Diclofenac Sodium IP 50mg (As Enteric coated tablet) Thiocolchicoside 8mg	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Novartis India Limited	Deferred in view of representation received from the company
(xvi)	Telmisartan + Amlodipine + Chlorthalidone Tablet	Each film coated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg,	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Zydus	9.30

		Chlorthalidone IP 6.25mg Tablets		Healthcare Limited	
(xvii)	Telmisartan + Amlodipine + Chlorthalidone Tablet	Each film coated tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Chlorthalidone 12.5mg Tablets	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Zydus Healthcare Limited	9.81
(xviii)	Clopidogrel + Aspirin tablet	Each tablet contains: Clopidogrel 75mg, Aspirin 75mg	1 Tablet	M/s Rivpra Formulation Pvt. Ltd. / M/s Cadila Pharmaceuticals Limited	3.31
(xix)	Teneligliptin + Metformin Tablet (TENELICAS M)	Each uncoated bilayered tablet contains: Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg Metformin HCl 500mg (ER)	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Anthus Pharmaceuticals Pvt. Ltd.	9.81
(xx)	Tenofovir Alafenamide Tablet (Tenocruz – AF)	Each film coated tablet contains: Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25mg	1 Tablet	M/s Hetero Labs Ltd./ M/s Torrent Pharmaceuticals Limited	44.29
(xxi)	Clarithromycin, Esomeprazole and Amoxicillin Tablets (Combi Pack)	Each Strip contains: a. Clarithromycin tablets IP 2 tablets: Each enteric coated tablet contains: Clarithromycin IP 500mg b. Esomeprazole Tablets IP 2 Tablets, Each film coated tablet contains: Esomeprazole Magnesium IP eq. to Esomeprazole 40mg, c. Amoxicillin Tablets USP 2 tablets, Each film coated tablet contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 750mg	Per Strip	M/s Malik Lifesciences Pvt. Ltd. / M/s Cipla Limited	136.80
(xxiii)	Darunavir + Ritonavir Tablet (Danavir 600 R)	Each film coated tablet contains: Darunavir Ethanolate eq. to Darunavir 600mg, Ritonavir 100mg Tablet	1 Tablet	M/s Hetero Labs Limited / M/s Hetero Healthcare Limited	160.71

B. Retail price fixed under para 5 and 15 of DPCO, 2013 (Pharmaeconomics cases)

Sl. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
(xxii)	Heavy Magnesium	Each film coated tablet Contains:	1	M/s Akums Drugs	5.08

	Oxide+ Vitamin C + Niacinamide + Zinc Oxide + Vitamin E + Calcium Pantothenate +Vitamin A + Cupric Oxide + Manganese Sulfate + Thiamine Mononitrate + Riboflavin + Pyridoxine Hydrochloride + Folic Acid + Chromium Picolinate + Biotin + Selenious Acid + Vitamin D3 + Methylcobalamin + L-Glutamic Acid + DL-Methionime Tablet (One up Gold D)	Heavy Magnesium Oxide IP 30mg, Vitamin C IP 100mg, Niacinamide IP 50mg, Zinc Oxide IP Eq. to Elemental Zinc 22.5mg, Vitamin E Acetate IP 25IU, Calcium Pantothenate IP 12.5mg, Vitamin A Concentrate Powder IP 5000IU, Cupric Oxide eq. to Elemental Copper 2.5mg, Manganese Sulfate Usp eq. to Elemental Manganese 2.5mg, Thiamine Mononitrate IP 10mg, Riboflavin IP 10mg, Pyridoxine Hydrochloride IP 3mg, Folic Acid IP 1500mcg, Chromium Picolinate USP eq. to Elemental Chromium 100mcg, Biotin USP 60mcg, Selenious Acid USP eq. to Elemental Selenium 60mcg, Vitamin D3 IP400IU, Methylcobalamin IP 500mcg, L-Glutamic Acid USP 100mg, DL-Methionime BP 25mg	Tablet	and Pharmaceuticals Limited / M/s Torrent Pharmaceuticals Limited	
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Note: The retail prices of new drugs will be notified after 10 days of uploading the draft working sheet.

5. Agenda item no. 5 – Status of review orders.

5.1 Noted.

5.2 Further, the Authority deliberated on the issue and observed that the five review orders with respect to the formulation ‘Ringer Lactate injection’ are pending since long and could not be implemented due to non submission/ submission of incorrect data by the companies. It was decided that relevant data be obtained from the concerned companies and the case for implementation of review orders be put up in the next meeting. In case the concerned companies fail to provide data timely, the matter shall be put up for rejection in the next meeting.

5.3 The Authority noted that the review order no. 31015/46/2017-Pricing dated 22.01.2018 relating to price fixation of Methyldopa 500 mg tablet vide SO. 787(E) dated 10.03.2017 issued for M/s Wockhardt Ltd has been referred back to Department of Pharmaceuticals with a request to forward the same to the Ministry of Corporate Affairs for further investigation in the matter. Therefore, the Authority decided to treat the review order as closed.

5.3 The Authority noted that the review order no. 31015/15/2014-PI.I dated 04.09.2018 relating to Ciprofloxacin Hydrochloride drops 0.3% issued for M/s Ranbaxy Laboratories Ltd (M/s Sun Pharmaceutical Industries Ltd) is pending since long. Accordingly, the Authority directed that the matter may be put up on file.

5.4 Agenda item no. 5(i) – Review application against retail price fixation of ‘Trilosar 6.25’ and ‘Trilosar 12.50’ tablet vide S.O. 5638(E) dated 02.11.2018 filed by (i) M/s Torrent Pharmaceuticals Ltd and (ii) M/s Unichem Laboratories Ltd.

5.4.1 The Authority deliberated upon the issue in detail and decided to revise the retail price of Trilosar 6.25 tablet and Trilosar 12.50 tablet to Rs. 6.85 per tablet and Rs. 7.10 per tablet respectively, excluding GST, for M/s GKM New Pharma Ltd/ M/s Unichem Laboratories Ltd.

6. Agenda item no. 6 - Submission of Form IV application by M/s. Abbott India Limited for discontinuation of scheduled formulation Forane (Isoflurane 100 ml & 250 ml) under para 21 (2) of DPCO, 2013.

6.1 The Authority examined the application M/s Abbott India Ltd to stop the production and supply of Forane (Isoflurane) formulations stating that their global supplier had stopped manufacturing the said products. It was decided to obtain additional data from the company regarding the quantities of current stock available, information on whether the company could source and supply the products from alternative sources and the period upto which the company would continue supply in India.

7. Agenda item no. 7 – Intimation of Minutes of 9th meeting of Multidisciplinary Committee of Experts held on 15.04.2019

7.1 Noted.

8. Agenda item no. 8 - Revision of ceiling price of scheduled formulation Silver Sulphadiazine Cream 1% under paragraph 19 of DPCO, 2013 – Communication from Rajasthan Medical Services Corporation Limited showing inability to procure the same at ceiling price notified by NPPA.

8.1 The Authority deliberated upon the issue and directed that the relevant data be obtained, for the month of August 2015, from the companies from whom representations have been received. It was decided that the requisite data shall be sought from the companies who

have participated in the tender process of Rajasthan Medical Services Corporation Ltd for procurement of Silver Sulphadiazine cream 1%. The Authority further directed NPPA to issue and upload an Office Memorandum requesting the other manufacturers/ marketers of Silver Sulphadiazine cream 1% to furnish relevant data for the month of August 2015 within 10 days of uploading of Office Memorandum.

9. Agenda item no. 9 – Form-IV applications submitted by M/s Neon Laboratories Ltd for discontinuation of 18 scheduled formulations under para 21(2) of DPCO, 2013

9.1 The Authority deliberated upon the issue at length and opined that since M/s Neon Laboratories Ltd supplies mainly to hospitals/ medical institutions directly, the market share of the company's formulations may not be correctly reflected in AIOCD-Pharmatrac data. The Authority directed that the company be called for explaining the reasons for the proposed discontinuation of its products.

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

Sd/-
(Ritu Dhillon)
Member Secretary