

मिसिल स.- 8(65)/2019/डी.पी/एनपीपीए-डीवी-॥

F. No. 8(65)/2019/DP/NPPA-Div. II

कार्यवाहीस. : 195/65/2019/F

Proceeding No : 195/65/2019/F

Minutes of the 197th (overall) and 65th meeting of the Authority under DPCO, 2013 held on 27.03.2019 at 11:00 AM

The 197th meeting of the Authority (overall), which is the 65th meeting under the DPCO, 2013, was held on the 27th of February, 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) Dr. S. Eswara Reddy, Drugs Controller General (India)
- (iii) Shri Arun Kumar, Advisor, Dept of Economic Affairs, Ministry of Finance
- (iv) Shri B. Bandyopadhyay, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Dr. M. Shaukat, Advisor (NCD), O/o the Director General of Health Service, Ministry of Health & Family Welfare attended the meeting as a special invitee.

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

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

- (i) Shri Kalyan Nag, Advisor
- (ii) Shri Amarपाल Singh Sawhney, Director (Pricing)
- (iii) Shri Nihal Pedric, Jt Director (Legal & Medical Devices)
- (iv) Shri Arun Kumar Diwan, Dy. Director (M&E)
- (v) Shri Prasenjit Das, Asstt. Director (Pricing)
- (vi) Shri Prakash Hemani, Asstt. Director (Pricing)
- (vii) Shri Alok Ranjan, Asstt. Director (Medical Devices)

Chairman, NPPA welcomed all present in the meeting.

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 63rd and 64th Meeting held on 21.02.2019 and 26.02.2019.

1.1 The Authority confirmed the minutes of the 195th (overall) & the 63rd and 196th (overall) & the 64th Meeting under DPCO 2013 held on 21.01.2019 and 26.02.2019 respectively.

2. Agenda item no. 2 – Action Taken Report

2.1 Noted.

2.2. The Authority noted with satisfaction the implementation of revision of prices based on trade margin rationalization by the manufacturers resulting in saving of almost Rs. 1000 crore per annum. It urged that through the monitoring mechanisms established by the orders issued, a rigorous implementation of the revised prices at all levels viz. hospitals/retailers/stockists/manufacturers be ensured. The Authority sought the co-operation of DCGI for effective monitoring and requested DCGI to issue necessary directions to the SDCs across the States for inspection of hospitals/retailers/stockists/manufacturers and e-pharmacies, to ensure strict compliance.

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

3.1 Noted.

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(xii) (total 22 Form I applications) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 21(twenty one) cases [except one case at sl no (vii)] 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 Approved (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
(i)	Sodium Fusidate + Halobetasole Cream	Cream contains: Sodium Fusidate IP eq. to Fusid Acid 2% w/w, Halobetasole Propionate USP 0.05% w/w	1 gm	M/s Apex Laboratories Private Limited	12.92
(ii)	Metformin + Glimpiride Tablet (Azulix 0.5 MF)	Each Uncoated Bilayered Tablet contains: Glimpiride IP 0.5mg, Metformin Hydrochloride IP 500mg (As Prolonged Release Form)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Limited	3.58

(iii)	Escitalopram + Clonazepam Tablet (Newcita Mini)	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 5mg, Clonazepam IP 0.5mg	1 Tablet	M/s Ravian Life Science Pvt. Ltd. / M/s Alkem Laboratories Ltd.	6.10
(iv)	Ceftriaxone + Sulbactum Injection (Taxone SB 1000mg)	Each vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 1gm Sulbactum Sodium USP eq. to Sulbactum 500mg	1 vial	M/s Mapra Laboratories Pvt. Ltd.	110.95
(v)	Ceftriaxone + Sulbactum Injection (Taxone SB 250mg)	Each vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 250gm Sulbactum Sodium USP eq. to Sulbactum 125mg	1 vial	M/s Mapra Laboratories Pvt. Ltd.	43.21
(vi)	Ceftriaxone + Sulbactum Injection (Taxone SB 500mg)	Each vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 500gm Sulbactum Sodium USP eq. to Sulbactum 250mg	1 vial	M/s Mapra Laboratories Pvt. Ltd.	71.60
(vii)	Alpha Lipoic + Methylcobalamin + Inositol USP + Folic Acid + Benfotiamine + Chromium Polynicotinate + Pyridoxine Hydrochloride Capsule	Each soft gelatine capsule contains: Alpha Lipoic Acid USP 200 mg, Methylcobalamin 1500 mcg, Inositol USP NF 100 mg, Folic Acid IP 105mg, Benfotiamine 150 mg, Chromium Polynicotinate 200 mg, Pyridoxine Hydrochloride IP 3 mg	1 Capsule	M/s Olive Healthcare / M/s Zydus Healthcare Limited	Deferred in view of representation from the company.
(viii)	Atorvastatin + Fenofibrate Tablet	Each film coated Tablet contains: Atorvastatin 10mg, Fenofibrate 160mg	Tablet	M/s Rivpra Formulations Pvt. Ltd. / M/s Cadila Pharmaceuticals Limited	11.52
(ix)	Hyaluronic Acid + Lidocain Hydrochloride Injection	Each ml contains: Hyaluronic Acid BP 24.0mg Lidocain Hydrochloride IP 3.00mg	Per pack having 2 prefilled syringe of 1 ml each	M/s Virchow Biotech Limited. / M/s Zydus Healthcare Limited	26987.40

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)
(x)	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/s Mylan Laboratories Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	44.29
	Tenofovir Alafenamide	Each film coated tablet contains: Tenofovir Alafenamide	1 Tablet	M/s Hetero Labs Ltd./ M/s Cipla Ltd.	44.29

	Tablet	Hemifumarate eq. to Tenofovir Alafenamide 25 mg			
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/s Hetero Labs Ltd./ M/s Cadila Healthcare Ltd.	44.29
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/s Hetero Labs Ltd./ M/s Emcure Pharmaceuticals Ltd.	44.29
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/ Natco Pharma Ltd. / M/s Sun Pharma Laboratories Ltd.	44.29
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/ Natco Pharma Ltd. / M/s Abbott India Ltd.	44.29
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/ Natco Pharma Ltd.	44.29
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/ Natco Pharma Ltd. / M/s Cadila Healthcare Ltd.	44.29
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/ Natco Pharma Ltd. / M/s Dr. Reddy's Laboratories Ltd.	44.29
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/ Natco Pharma Ltd. / M/s Aprazer Healthcare Pvt. Ltd.	44.29
(xi)	Emtricitabine + Tenofovir Alafenamide tablet (Tafmune – EM)	Each film coated tablet contains: Emtricitabine IP 200 mg Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 25 mg	1 Tablet	M/s Hetero Labs Ltd. / M/s Cipla Ltd.	55.33
	Tenofovir Alafenamide+ Emtricitabine Tablet (TAFICITA)	Each film coated contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25mg, Emtricitabine 200mg	1 Tablet	M/s Mylan Laboratories Ltd. / M/s Mylan Pharmaceuticals Pvt. Ltd.	55.33
(xii)	Emtricitabine + Tenofovir Alafenamide Tablet	Each film coated tablet contains: Emtricitabine IP 200mg, Tenofovir Alafenamide Hemifumarate eq. to Tenofovir Alafenamide 10mg	1 Tablet	M/s Hetero Labs Limited / M/s Cipla Limited	31.17

4.2 Agenda item no. 4(xiii) - Applications for retail price fixation of new drug where specific approval from DCGI has not been furnished by the companies.

The Authority deliberated the cases in details and decided as follows:

Sl. No.	Formulation	Manufacturing Company	Marketing Company	Date of Application	Decisions of the Authority
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1.	Each coated Granules contains: Mesalazine IP 2mg (As Coated Granules)	M/s Sun Pharma Laboratories Limited	M/s Sun Pharma Laboratories Limited	21.08.2018	It was decided to fix the retail price of the subject formulation as four years have passed since its first import approval granted by DCGI
2.	Each coated Granules contains: Mesalazine IP 1mg (As Coated Granules)	M/s Sun Pharma Laboratories Limited	M/s Sun Pharma Laboratories Limited	21.08.2018	
3.	Each uncoated bilayered tablet contains: Glimepiride IP 1mg, Metformin Hydrochloride IP 1000mg (in Sustained release form), Voglibose 0.2mg	M/s Windlas Biotech Ltd.	M/s Intas Pharmaceuticals Limited	08.11.2018	It was decided to reject the form I application, since specific approval from DCGI is not available.
4.	Each uncoated bilayered tablet contains: Glimepiride IP 2mg, Metformin Hydrochloride IP 1000mg (in Sustained release form), Voglibose 0.2mg	M/s Windlas Biotech Ltd.	M/s Intas Pharmaceuticals Limited	08.11.2018	
5.	Each ml contains: Diclofenac Sodium IP 75mg, Benzyl Alcohol IP 4% v/v (As Preservative) Water for Injection	M/s Bio-Medica Laboratories Pvt. Ltd.	M/s Bio-Medica Laboratories Pvt. Ltd.	19.11.2018	It was decided to reject the form I application with direction to obtain NOC from DCGI and apply afresh.
6.	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg, (As film coated tablet) Aspirin IP 75mg, (As Enteric coated pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet)	M/s Pure and Cure Healthcare Pvt. Ltd.	M/s Zydus Healthcare Limited	04.12.2018	It was decided to reject the form I application with direction to obtain NOC from DCGI showing specific strength of the formulation and apply afresh.
7.	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg, (As film coated tablet) Aspirin IP 75mg, (As Enteric coated pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As film coated tablet)	M/s Pure and Cure Healthcare Pvt. Ltd.	M/s Zydus Healthcare Limited	04.12.2018	
8.	Each film coated tablet contains: Metformin Hydrochloride IP 500mg, Glimepiride IP 3mg	M/s Macleods Pharmaceutical Limited	M/s Macleods Pharmaceutical Limited	24.12.2018	It was decided to reject the form I application with direction to obtain NOC from DCGI and apply afresh
9.	Each film coated tablet contains: Metformin Hydrochloride	M/s Macleods Pharmaceutical Limited	M/s Macleods Pharmaceutical Limited	24.12.2018	

	IP 500mg, Glimepiride IP 4mg				
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5. Agenda item no. 5 – Status of implementation of review orders.

5.1 Noted.

6. Agenda item no. 6 - Presentation of Data for price fixation of Liposomal Amphotericin B as per ‘Working sheet related to price notified on 28th June 2013 under DPCO, 2013’ (Ref: Order dated 05.02.2019 passed by Hon’ble High Court of Delhi at New Delhi in W.P. (C) No. 5078/201).

6.1 The Authority deliberated upon the issue in detail and observed that based on Hon’ble Delhi High Court’s direction, the separate ceiling price is to be fixed for ‘Amphotericin B Lipid injection’ and ‘Amphotericin B Liposomal injection’ by taking the pricing data of “material time in April 2013.” The Authority in compliance of the directions of the Hon’ble High Court accepted the separate price fixation of ‘Amphotericin B Lipid injection’ and ‘Amphotericin B Liposomal injection’. However, it noted that the ceiling price worked out on the basis of data of “material time in 2013” would result in a substantial increase in the ceiling price of Amphotericin B (liposomal) injection, leading to a very high expense to be borne by the patients which may not be in public interest at large. Therefore, the Authority desired that this may be brought to the kind notice of Hon’ble High Court through an appeal and the plea may be made before the Hon’ble High Court to reconsider the directions given in the case and allow for the data of the year 2015 (August) to be utilized for the recomputation of Amphotericin B (liposomal) injection.

7. Agenda item no. 7 – Ceiling Price revision based on Wholesale Price Index (WPI) as per para 16(2) of DPCO, 2013 w.e.f 01.04.2019

7.1 The Authority deliberated on the issue and approved the WPI @ 4.2662% to be applicable on scheduled formulations w.e.f 01.04.2019. The Authority also approved the revised ceiling price of the scheduled formulations based on WPI @ 4.2662% to be effective from 01.04.2019.

8. Agenda item no. 8 - Agenda for deliberation of the Authority with regard to following issues raised by the Pharmaceutical Industry & their Associations with regard to provisions under Para 2 (2) and Para 20 of the DPCO, 2013-reg.

8.1 The Authority deliberated the issue of applicability of DPCO, 2013 in respect of Medical Devices being raised by the various Industry Associations from time to time and observed that Para 20 of the DPCO, 2013, empowers NPPA to monitor MRP of all the medical devices which have been declared/regulated as 'Drugs' under Drugs & Cosmetics Act, 1940. Accordingly, the Authority opined that NPPA is rightly monitoring the MRP of medical devices which have been declared/regulated as 'Drugs' under Drugs & Cosmetics Act, 1940 from 15th May 2013 i.e. from the date of applicability of DPCO, 2013.

8.2 The Authority observed that Para 20(1) of the DPCO, 2013 is a self regulatory provision for the companies who are complying with the provision. At the same time, this provision is a deterrent one for the non-compliant. Therefore, the Authority found that no notional increase would be allowed while computing overcharged amount to the non compliant companies. Accordingly, the Authority decided to empower NPPA to initiate overcharging cases against the errant companies as per extant practice.

8.3 The Authority also noted provision of Para 20(2) of the DPCO, 2013 and opined that the errant companies shall be liable to pay interest on overcharged amount from the date of overcharging till the date of compliance of the provisions of the Para 20 of the DPCO, 2013.

9. Agenda item no. 9 - Minutes of the 8th meeting of Multidisciplinary Committee of Experts held on 18.03.2019.

9.1 Noted.

10. Agenda item no. 10 - Review order No. 31015/46/2017 dated 22.01.2018 relating to price fixation of Methyldopa 500mg Tablet vide SO 787(E) dated 10.03.2017 for M/s Wockhardt Limited. (regarding Internal Inquiry Report)

10.1 The Authority deliberated upon the issue and decided to refer the matter to Department of Pharmaceuticals with a request to forward the same to the Ministry of Corporate Affairs for further investigation in the matter.

11. Agenda item no. 11 - Request for pricing of product ATTUNE S+™ of Tibial Component of Orthopaedic Knee Implant of M/s Johnson and Johnson.

11.1 The Authority deliberated upon the matter in detail and decided to accept the recommendation of the Multidisciplinary of Experts to reject the claim of M/s Johnson and Johnson for price revision of ATTUNE S+™ of Tibial Component of Orthopaedic Knee Implant. The Authority also directed that the matter may be referred to DCGI to examine the safety concerns regarding this product, raised in recent reports and publications.

12. Agenda item no. 12 – Form-IV applications submitted by Serum Institute of India Pvt. Ltd. for discontinuation of scheduled formulations Diphtheria, Tetanus & Pertussis(DPT) vaccine 0.5ml, Tetanus Toxoid(TT) vaccines 0.5ml & 5ml; and Diphtheria & Tetanus(TD) vaccine 0.5 ml under para 21 (2) of DPCO, 2013

12.1 The Authority directed to issue reminder letter to Department of Pharmaceuticals for invoking para 3 of DPCO, 2013. Further, a record note for members is being separately circulated.

13. Agenda item no. 13 – Revision of Ceiling price of Stents.

13.1 The Authority deliberated upon the issue in detail and noted that the ceiling price of coronary stents, was fixed under para 19 of DPCO, 2013 in the year 2017 vide S.O. 412(E) dated 13.02.2017 & S.O. 1041(E) dated 01.04.2017 and in the year 2018 vide S.O. 639(E) dated 12.02.2018 and S.O 1464(E) dated 02.04.2018. Coronary stents being scheduled formulation, the ceiling price fixed vide S.O. 639(E) dated 12.02.2018 and S.O 1464(E) dated 02.04.2018 is to be given a Wholesale Price Index (WPI) revision under para 16 of DPCO, 2013. Accordingly, the Authority decided to revise the ceiling price of coronary stents based on WPI @ 4.2662%, to be effective from 01.04.2019, as detailed below:

Sl No.	Coronary Stents	Ceiling Prices with WPI w.e.f. 01/04/2019 (₹)
1	Bare Metal Stents	8,261
2	Drug Eluting Stents (DES) including metallic DES and Bioresorbable Vascular Scaffold (BVS)/ Biodegradable Stents	30,080

14. Agenda item no. 14 - Upward revision of ceiling price of medicines under para 19 of the DPCO 2013.

14.1 Record note for members being circulated separately.

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

Sd/-
(Ritu Dhillon)
Member Secretary