

मिसिल स.- 8(62)/2018/डी.पी/एनपीपीए-डीवी-॥

F. No. 8(62)/2018/DP/NPPA-Div. II

कार्यवाहीस. : 194/62/2019/F

Proceeding No : 194/62/2019/F

**Minutes of the 194<sup>th</sup> (overall) and 62nd meeting of the Authority under DPCO, 2013 held on 21.01.2019 at 10.15 AM**

The 194<sup>th</sup> meeting of the Authority (overall), which is the 62<sup>nd</sup> meeting under the DPCO, 2013, was held on the 21<sup>st</sup> of January, 2019 at 10.15 AM under the Chairpersonship of Ms. Shubhra Singh, Chairperson, 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) 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 Amarpal Singh Sawhney, Director (Pricing)
- iii. Shri Baljit Singh, Asstt. Director (Pricing)
- iv. Shri Prasenjit Das, Asstt. Director (Pricing)
- v. Shri Prakash Hemani, Asstt. Director

1.2 Chairperson, NPPA welcomed all present in the meeting.

**II. Agenda items**

**1. Agenda item no. 1 - Confirmation of Minutes of the 61ST Meeting held on 19.12.2018**

1.1 The Authority confirmed the minutes of the 193rd (overall) and the 61st Meeting under DPCO 2013 held on 19.12.2018.

**2. Agenda item no. 2 – Action Taken Report**

2.1 Noted.

**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 noted that NPPA is displaying the worksheet of retail price fixation of new drugs for 10 days prior to bringing them before the Authority for greater transparency. The

Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (total 45 Form I applications) falling under the purview of para 2(u) of DPCO, 2013 and approved the retail prices in 41(Forty One) cases [except case at sl no (iv), (v) , (xii) and (xviii)], 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 (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
i	Telmisartan + Cilnidipine + Chlorthalidone tablet	Each film coated tablet contains: Telmisartan IP 40mg, Cilnidipine 10mg, Chlorthalidone 6.25mg	Tablet	M/s Windlas Biotech Private Limited / M/s Eris Lifesciences Ltd.	10.43
ii	Paracetamol + Diclofenac Sodium Tablet	Each film coated tablet contains: Paracetamol IP 325mg Diclofenac Sodium IP 50mg	Tablet	M/s Indoco Remedies Limited	3.29
iii	Atorvastatin + Clopidogrel Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg Clopidogrel Bisulphate IP eq. To Clopidogrel 75mg	Capsule	M/s Windlas Biotech Private Limited / M/s Aprica Healthcare Pvt. Limited	12.09
iv	Glimepiride + Metformin Hydrochloride + Voglibose Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 1mg, Metformin Hydrochloride IP 1000mg (in Sustained release form), Voglibose 0.2mg	Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Intas Pharmaceuticals Limited	Deferred [as at (i) of the notes]
v	Glimepiride + Metformin Hydrochloride + Voglibose Tablet	Each uncoated bilayered tablet contains: Glimepiride IP 2mg, Metformin Hydrochloride IP 1000mg (in Sustained release form), Voglibose 0.2mg	Tablet	M/s Windlas Biotech Pvt. Ltd. / M/s Intas Pharmaceuticals Limited	Deferred [as at (i) of the notes]
vi	Paracetamol + Phenylephrine HCL + Caffeine + Diphenhydramine HCL Tablet	Each uncoated tablets contains: Paracetamol IP 500mg, Phenylephrine HCL IP 5mg, Caffeine (Anhydrous) IP 30mg, Diphenhydramine HCL IP 25mg	Tablet	M/s KonTest Chemicals Limited	2.70
vii	Drotaverine Hydrochloride + Diclofenac Potassium Tablet	Each tablet contains; Drotaverine Hydrochloride 80mg, Diclofenac Potassium 50mg	Tablet	M/s Cris Pharma (India) Limited / M/s Seagull Pharmaceuticals Pvt. Ltd.	7.17
viii	Atorvastatin +	Each hard gelatine capsule	Capsule	M/s Windlas	17.50

	Clopidogrel Capsule	contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg		Biotech Private Limited / M/s Aprica Healthcare Pvt. Limited	
ix	Rosuvastatin + Clopidogrel Capsule	Each hard gelatine capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	Capsule	M/s Windlas Biotech Private Limited / M/s Aprica Healthcare Pvt. Limited	13.13
x	Rosuvastatin + Clopidogrel Capsule	Each hard gelatine capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	Capsule	M/s Windlas Biotech Private Limited / M/s Aprica Healthcare Pvt. Limited	17.16
xi	Mesalazine Tablet (5 –aminosalicylic acid)	Each uncoated tablet contains: Mesalazine IP Prolonged Release 500mg	1 Tablets	M/s Sun Pharmaceutical Industries Limited / M/s Sun Pharma Laboratories Limited	22.32
xii	Hyaluronic Acid + Lidocain Hydrochloride Injection	Each ml contains: Hyaluronic Acid BP 24.0mg Lidocain Hydrochloride IP 3.00mg	2*1 ML (Each Pack)	M/s Virchow Biotech Limited. / M/s Zydus Healthcare Limited	Deferred [as at (ii) of the notes]
xiii	Diclofenac Sodium + Chlorzoxazone Tablet (Diclotal M)	Each Film coated Tablet Contains: Diclofenac Sodium IP 50mg, Chlorzoxazone USP 500mg	Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	4.56
xiv	Griseofulvin Tablet (Grisovin FP)	Each uncoated tablet contains: Griseofulvin IP 500mg	Tablet	M/s GlaxoSmithKline Pharmaceuticals Ltd.	8.15 [as at (iii) of the notes]
xv	Telmisartan + Amlodipine + Hydrochlorothiazide Tablet (TELMIWOCK-AMH)	Each uncoated tablet contains: Telmisartan IP 40mg, Amlodipine Besilate IP 5mg, Hydrochlorothiazide 12.5mg	Tablet	M/s Pure & Cure Healthcare Pvt. Limited / M/s Wockhardt Limited	7.88
xvi	Metformin HCL + Glimepiride Tablet (Glitop-M1)	Each uncoated bilayer tablet contains: Metformin HCL IP 500mp (As SR), Glimepiride IP 1mg	Tablet	M/s Pharmafabrikon	4.00
xvii	Metformin HCL + Glimepiride Tablet (Glitop-M2)	Each uncoated bilayer tablet contains: Metformin HCL IP 500mp (As	Tablet	M/s Pharmafabrikon	5.00

		SR), Glimepiride IP 2mg			
xviii	Diclofenac Sodium + Benzyl Alcohol Water for Injection	Each ml contains: Diclofenac Sodium IP 75mg, Benzyl Alcohol IP 4% v/v (As Preservative)	1 ML	M/s Bio-Medica Laboratories Pvt. Ltd.	Deferred [as at (iv) of the notes]
xix	Amoxicillin + Potassium Clavulanate Tablet	Each un-coated dispersible tablet contains: Amoxicillin Trihydrate eq. to Amoxicillin IP 200mg Plus Potassium clavulanate diluted eq. to Clavulanic Acid IP 28.5mg	Tablet	M/s Medicef Pharma / M/s Emcure Pharmaceuticals Ltd.	7.46
xx	Atorvastatin Tablet	Each tablet contains: Atorvastatin 80mg Tablet	Tablet	M/s Cadila Pharmaceuticals Limited	27.54
xxi	Voglibose + Metformin HCL Tablet	Each Uncoated tablet contains: Voglibose IP 0.3mg, Metformin HCL IP 500mg	Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Eris Lifesciences Ltd.	8.42
xxii	Metoprolol Tartrate + Ramipril Tablet	Each uncoated bilayer tablet contains: Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (As ER) 50mg Ramipril IP 5mg	Tablet	M/s Lupin Limited / M/s Aprica Healthcare Pvt. Limited	15.63 [as at (v) of the notes]
xxiii	Rosuvastatin + Clopidogrel + Aspirin Capsule (Sultatin Gold 20)	Each Hard gelatine Capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As Pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets), Aspirin IP 75mg (As Enteric Coated Tablet)	Capsule	M/s Synokem Pharmaceuticals Limited / M/s Medopharma	16.07
xxiv	Methylcobalamin + Alpha Lipoic Acid + Pyridoxine Hydrochloride +, Folic Acid + Vitamin D3 Tablet (Nervijen D3)	Contains: Methylcobalamin IP 1500mcg, Alpha Lipoic Acid USP 100mg, Pyridoxine Hydrochloride IP 3mg, Folic Acid IP 1.5mg, Vitamin D3 IP 1000IU	Tablet	M/s Akums Drugs & Pharmaceuticals Pvt. Ltd. / M/s Jenburkt Pharmaceuticals Ltd.	10.26
xxv	Amoxicillin + Potassium Clavulante Tablet (NEW NUMOX KID)	Each un-coated dispersible tablet contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 200mg, Potassium Clavulante Diluted IP eq. to Clavulnic Acid 28.5mg	Tablet	M/s Malik Lifesciences Pvt. Ltd. / M/s Jenburkt Pharmaceuticals Ltd.	7.46
xxvi	Atorvastatin Calcium + Aspirin Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg Aspirin IP 75mg	Capsule	M/s Windlas Biotech Private Limited / M/s Aprica Healthcare Pvt. Limited	2.25

xxvii	Cilnidipine + Telmisartan Tablet	Each film coated tablets contains: Cilnidipine IP 10mg, Telmisartan IP 80mg	Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	10.54
xxviii	Cefixime + Dicloxacillin Tablet	Each film coated tablets contains: Cefixime IP as Trihydrate eq. to Anhydrous Cefixime 200mg, Dicloxacillin Sodium IP eq. to Anhydrous Dicloxacillin 500mg (ER)	Tablet	M/s Khandelwal Laboratories Pvt. Ltd. / M/s Mankind Pharma Ltd.	16.48
xxix	Telmisartan + Chlorthalidone +Amlodipine Tablets	Each film coated bilayered tablet contains: Telmisartan IP 80mg Chlorthalidone IP 6.25mg Amlodipine 5mg Tablets	Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Limited	14.73
xxx	Telmisartan + Chlorthalidone +Amlodipine Tablets	Each film coated bilayered tablet contains: Telmisartan IP 80mg Chlorthalidone IP 12.50mg Amlodipine 5mg Tablets	Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Limited	14.43
xxxi	Telmisartan + Chlorthalidone +Amlodipine Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40mg Chlorthalidone IP 6.25mg Amlodipine 5mg Tablets	Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Limited	9.30
xxxii	Telmisartan + Chlorthalidone +Amlodipine Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40mg + Chlorthalidone IP 12.50mg +Amlodipine 5mg Tablets	Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Alembic Pharmaceuticals Limited	9.65
xxxiii	Metoprolol Tartrate + Ramipril Tablet	Each uncoated bilayer tablet contains: Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (As ER) 25mg Ramipril IP 5mg	Tablet	M/s Lupin Limited / M/s Aprica Healthcare Pvt. Limited	10.29 [as at (v) of the notes]

Note :

- (i) Approval of DCGI, in Form 45 or Form 46, to be seen.
- (ii) Further inputs from DCGI to be obtained.

- (iii) The representation of M/s GlaxoSmithkline Pharmaceuticals Ltd was examined by the Authority and its contention was not found acceptable.
- (iv) Further inputs from DCGI to be obtained.
- (v) The representation of M/s Lupin Ltd was examined by the Authority and its contention was not found acceptable.

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

<b>Sl. No.</b>	<b>Name of the Formulation / Brand Name</b>	<b>Strength</b>	<b>Unit</b>	<b>Manufacturer &amp; Marketing Company</b>	<b>Retail Price (Rs.)</b>
i	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	Tablet	M/s Mylan Laboratories Ltd./ M/s Mylan Pharmaceuticals Pvt. Ltd.	44.29 [as at (vi) of the notes]
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	Tablet	M/s Hetero Labs Ltd./ M/s Cipla Ltd.	44.29 [as at (vi) of the notes]
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	Tablet	M/s Hetero Labs Ltd./ M/s Cadila Healthcare Ltd.	44.29 [as at (vi) of the notes]
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	Tablet	M/s Hetero Labs Ltd./ M/s Emcure Pharmaceuticals Ltd.	44.29 [as at (vi) of the notes]
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	Tablet	M/ Natco Pharma Ltd. / M/s Sun Pharma Laboratories Ltd.	44.29 [as at (vi) of the notes]
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	Tablet	M/ Natco Pharma Ltd. / M/s Abbott India Ltd.	44.29 [as at (vi) of the notes]
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	Tablet	M/ Natco Pharma Ltd.	44.29 Refer Note (vi)
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	Tablet	M/ Natco Pharma Ltd. / M/s Cadila Healthcare Ltd.	44.29 [as at (vi) of the notes]
	Tenofovir	Each film coated tablet	Tablet	M/ Natco Pharma	44.29 [as at

	Alafenamide Tablet	contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg		Ltd. / M/s Dr. Reddy's Laboratories Ltd.	(vi) of the notes]
	Tenofovir Alafenamide Tablet	Each film coated tablet contains: Tenofovir Alafenamide fumarate eq. to Tenofovir Alafenamide 25 mg	Tablet	M/ Natco Pharma Ltd. / M/s Aprazer Healthcare Pvt. Ltd.	44.29 [as at (vi) of the notes]
ii	Emtricitabine + Tenofovir tablet (Tafmune – EM)	Each film coated tablet contains: Emtricitabine IP 200 mg Tenofovir Alafenamide Hemifumarate eq to Tenofovir Alafenamide 25 mg	Tablet	M/s Hetero Labs Ltd. / M/s Cipla Ltd.	55.33 [as at (vi) of the notes]
iii	Abacavir + Dolutegravir + Lamivudine tablet	Each film coated tablet contains: Abacavir Sulphate IP eq. to Abacavir 600 mg Dolutegravir Sodium eq. to Dolutegravir 50 mg Lamivudine IP 300 mg	Tablet	M/s Emcure Pharmaceuticals Ltd.	157.96 [as at (vi) of the notes]

Note :

(vi) The Authority directed NPPA to notify the price after 10 days from the date of uploading of minutes of the 6th meeting of the Multidisciplinary Committee of Experts held on 15.01.2019.

## 5. Agenda item no. 5 – Status of Review order.

5.1 Noted. The Authority further directed NPPA to give age wise pendency of review orders, in the status note, for the subsequent meetings.

## 6. Application for exemption under para 32 of DPCO, 2013.

6.1 The Authority noted that so far only 3(three) cases have been granted exemption under para 32 of DPCO, 2013. All the applications received were examined at Committee level before coming up for consideration before the Authority. A Committee was earlier constituted by NPPA vide letter dated 24.07.2013 which was subsequently superseded by a new Multidisciplinary Committee of Experts constituted by Deptt of Pharmaceuticals vide order dated 30.11.2017, where, inter-alia, the matters relating to para 32 of DPCO, 2013 have also been covered.

## 6.2 Application of M/s Meril Life Sciences Pvt Ltd for Exemption under para 32(ii) of DPCO, 2013 for their product Sirolimus Eluting BioResorbable vascular scaffold system (MeRes100)

6.2.1 The Authority noted that Deptt of Pharmaceuticals vide its letter dated 31.12.2018 directed NPPA that as per Government of India's Resolution dated 29.08.1997, NPPA has the power to regulate its procedure for performing the functions entrusted to NPPA. Hence, NPPA is competent to decide procedure/ methodology for deciding cases under para 32 of DPCO, 2013. After detailed deliberations, the Authority decided to refer the case to the Multi Disciplinary Committee of Experts, which after co-opting suitable expert/(s) in the Committee, shall make recommendation to the Authority.

**6.3 Application of M/s Sun Pharmaceutical Industries Ltd for Exemption under para 32 of DPCO, 2013 for their product Volitra APS Diclofenac Diethylamine and absolute Alcohol.**

6.3.1 The Authority noted that M/s Troikaa Pharmaceutical Ltd, in whose name the patent has been granted had launched this product in year June, 2013. Therefore, the period of five years from the date of commencement of its commercial marketing, by the manufacturer, in the country is over. Therefore, M/s Sun Pharmaceutical Industries Ltd is not eligible for the exemption of the said product. Hence, the application of M/s Sun Pharmaceutical Industries Ltd, under para 32, was rejected by the Authority.

**6.4 Application of M/s Sun Pharmaceutical Industries Ltd for Exemption under para 32 (ii) of DPCO, 2013 for their product Gemcitabine hydrochloride injection 10mg/ml (Ready to use infusion bags 1200mg/120ml, 1400mg/140ml and 1600mg/160ml).**

6.4.1 After detailed deliberations, the Authority decided to refer the case to the Multi Disciplinary Committee of Experts, which after co-opting suitable expert/(s) in the Committee, shall make recommendation to the Authority.

**7. Agenda item no. 7 – Upward revision of ceiling price of medicines under para 19 of the DPCO 2013**

7.1 Records of discussion for members being circulated separately.

**8. Agenda item no. 8 - Minutes of the 6<sup>th</sup> meeting of Multidisciplinary Committee of Experts held on 15.01.2019.**

8.1 Noted.

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

(Ritu Dhillon)  
Member Secretary