

मिसिलस.- 8(107)/2023/डी.पी/एनपीपीए-डीवी-II
F. No. 8(107)/2023/DP/NPPA-Div. II

कार्यवाहीस. : 239/107/2023/F
Proceeding No: 239/107/2023/F

Minutes of the 239th(overall) and 107thmeeting of the Authority under DPCO, 2013 held on 11.01.2023 at 11:00AM

The 239thmeeting of the Authority (overall), which is the 107thmeeting under the DPCO, 2013, was held on 11thof January, 2023 at 11:00 AM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri G. Venkatesh, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) Shri Saikat Sarkar, Economic Advisor, Department of Economic Affairs

Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare was also was present.

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

- (i) Shri Manmohan Sachdeva, Advisor (Cost-I)
- (ii) Shri Sanjay Kumar, Advisor (Cost-II)
- (iii) Shri G.L. Gupta, Director (M&E)
- (iv) Shri Jegan, Joint Director (Overcharging)
- (v) Shri Saurabh Bansal, Deputy Director (M&E)
- (vi) Shri Mahaveer Saini, Deputy Director (Pricing)
- (vii) Shri Rajesh T, Deputy Director (Medical Devices)
- (viii) Ms. Yuvika Panwar, Assistant Director (Overcharging /Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 106thMeeting held on 30.12.2022.

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 - (a) Action Taken Report (ATR) on decisions taken by NPPA in its 106thMeeting held on 30.12.2022.

2.1 Noted.

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

3.1 Noted.

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4. Agenda item no. 4 – New Drug applications for Price fixation under Para 5 and Para 15 of DPCO, 2013

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) (a total of 12 Form I applications containing retail price fixation of 12 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 12(Twelve) new drugs under Para 5 and 15 of the DPCO 2013, as detailed in **Table 1:**

Table No. 1: Retail price fixation of new drugs

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Glimepiride, Voglibose & Metformin Hydrochloride 500mg (as Extended-release form) tablet	Each uncoated bilayered tablet contains: Glimepiride IP 2mg, Voglibose IP 0.2mg Metformin Hydrochloride IP 500mg (as Extended-release form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Apex Laboratories Pvt. Ltd.	13.83
4(ii)	Paracetamol, Phenylephrine Hydrochloride, Diphenhydramine Hydrochloride and Caffeine tablet	Each uncoated tablet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 5mg Diphenhydramine Hydrochloride 25 mg Caffeine (Anhydrous) IP 30mg	1 Tablet	M/s Alicon Pharmaceuticals Pvt. Ltd. / M/s Dales Laboratories Pvt. Ltd.	2.76
4(iii)	Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine tablet	Each film coated tablet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 10mg Chlorpheniramine maleate IP 2mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Limited	4.36
4(iv)	Desvenlafaxine (as extended-release form) and Clonazepam tablet	Each uncoated bilayered tablet contains: Desvenlafaxine Succinate USP eq. to Desvenlafaxine 50mg (as extended-release form) Clonazepam IP 0.25mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	13.24
4(v)	Thiocolchicoside + Aceclofenac + Paracetamol tablet	Each film coated tablet contains: Thiocolchicoside IP 8mg Aceclofenac IP 100 mg Paracetamol IP 325 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	24.78
4(vi)	Telmisartan,	Each film coated	1 Tablet	M/s Ravenbhel	

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Chlorthalidone & Metoprolol ER tablet	bilayered tablet contains: Telmisartan IP 40mg Chlorthalidone IP 12.5mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as Extended release) 25mg		Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	10.90
4(vii)	Telmisartan, Chlorthalidone & Metoprolol ER tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg Chlorthalidone IP 12.5mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as Extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	13.15
4(viii)	Rosuvastatin & Clopidogrel capsule	Each Hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	1 Capsule	M/s Windlas Biotech Limited. / M/s Modi-Mundipharma Pvt. Ltd.	13.66
4(ix)	Rosuvastatin & Clopidogrel capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	1 Capsule	M/s Windlas Biotech Limited. / M/s Modi-Mundipharma Pvt. Ltd.	16.96
4(x)	Rosuvastatin, Clopidogrel & Aspirin capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 75mg	1 Capsule	M/s Windlas Biotech Limited. / M/s Modi-Mundipharma Pvt. Ltd.	20.53
4(xi)	Montelukast and Acebrophylline (SR) tablet	Each uncoated bilayered tablet contains: Montelukast Sodium IP eq. to Montelukast 10mg Acebrophylline 200mg (As Sustained release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Zydus Healthcare Limited	16.12
4(xii)	Pantoprazole tablet	Each enteric coated tablet contains: Pantoprazole Sodium	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Torrent	6.68 (Note 1)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		IP eq. to Pantoprazole 20mg		Pharmaceuticals Limited	

Note 1. The Authority was informed that applicant M/s Torrent Pharmaceuticals Limited in their Form-I application claimed retail prices of Rs. 7.50/10 tablets excluding taxes. Accordingly, the draft worksheet uploaded proposing the retail price of Rs. 0.75 per tablet excluding taxes. However, it was informed that the company i.e. M/s Torrent Pharmaceuticals Limited has made a representation dated 22.12.2022 stating that "Due to typo error we have erroneously mentioned retail price excluding taxes claim for approval Rs. 7.50/10 tablet in place of Rs. 7.5/1 tablet excluding taxes". The Authority deliberated on the matter and noted that PTR of other company brands with more than 1% market share are in the range of Rs. 2.84/ tablet to Rs. 8.27/ tablet and the average PTR is Rs. 5.76/ tablet. In view of this, Authority decided to consider the representation of the company and approved retail prices as worked out to Rs. 6.68 per tablet excluding taxes, though the claim of the company is on higher side i.e. Rs. 7.50 per tablet excluding taxes.

5. Agenda item no. 5 – Status of implementation of Review cases

5.1 Noted.

6. Agenda item no. 6 –Fixation of Ceiling Price of scheduled formulations under Revised Schedule-I (NLEM, 2022).

6.1 The Authority noted that the methodology for fixation of ceiling price of scheduled formulations under revised Schedule-I (NLEM, 2022) was deliberated in the 104th meeting of Authority held on 23.11.2022. Based on the approved methodology, ceiling prices for 134 formulations were uploaded on NPPA website for 10 working days to invite comments in compliance to O.M. No. F. NO. 31015/44/2016-PI.I dated 11.07.2016 issued by Department of Pharmaceuticals as detailed in **Table 2:**

Table No. 2: Status of draft working sheets uploaded

S.No.	Date of upload of draft working sheets	10 days completed on	No. of formulations uploaded	Approved in 106 th meeting	No. of formulations proposed for approval
1.	13.12.2022	27.12.2022	69	3	64
2.	20.12.2022	03.01.2023	30	-	30
3.	23.12.2022	06.01.2023	35	-	34
	Total		134	3	128

Note: Total 3 formulations are proposed to defer as 2 formulations of Sodium Valproate and 1 formulation Clotrimazole Lotion 1% requires re-upload.

6.2 The Authority was informed that 693 representations were received from companies till 06.01.2023, within the prescribed time lines of 10 days. The companies have submitted copies of invoice(s) showing the revised PTR and snapshots of sample pack(s) showing revised MRP. The representations broadly covered the following:

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(a) Related to data in worksheets:

- i. Price to Retailer considered as per July, 2022 Pharmatrac database is not reflecting the WPI increase availed by the companies in April, 2022
- ii. Incorrect pack sizes
- iii. Considering MR variant along with conventional variant in cases where MR variant is separately included in schedule.

(b) Related to methodology:

- i. Representations received on methodology are same as already deliberated in 105th meeting of Authority held on 15.12.2022.

6.3 Authority noted that there was price revision in 71 formulations as compared to the ceiling prices reflected in the draft uploaded working sheets. The Authority deliberated and approved the ceiling prices of 128 formulations as appearing in column (7) of the **Table 3.**

Table 3: Ceiling Prices of 128 formulations

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Prices with immediate effect	Unit
				Rs./Unit	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1	18.6.2	Levothyroxine	Tablet 62.5mcg	1.56	(S.O. 1499(E) dated 30.03.2022)	1.44	1 Tablet
2	7.4.14	Ondansetron	Tablet 4 mg	5.23	(S.O. 1499(E) dated 30.03.2022)	4.58	1 Tablet
3	6.7.5.3	Clindamycin	Tablet 300mg	16.93	(S.O. 1499(E) dated 30.03.2022)	16.92	1 Tablet
4	7.2.4	Prednisolone	Tablet 40mg	3.12	(S.O. 1499(E) dated 30.03.2022)	3.04	1 Tablet
5	7.4.16	Zoledronic acid	Powder for Injection 4mg	4664.74	(S.O. 1499(E) dated 30.03.2022)	2133.32	1 Vial
6	10.2.1	Adenosine	Injection 3mg/mL	109.33	(S.O. 1499(E) dated 30.03.2022)	82.81	1 ML
7	16.2	Ciprofloxacin	Drops 0.3 %	1.69	(S.O. 1499(E) dated 30.03.2022)	1.37	1 ML

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Prices with immediate effect	Unit
				Rs./Unit	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
8	1.1.2	Isoflurane	Liquid for inhalation	11.61	(S.O. 1499(E) dated 30.03.2022)	8.61	1 ML
9	7.1.15	Cytosinearabioside	Injection 1000mg/vial	1189.78	(S.O. 1499(E) dated 30.03.2022)	1008.07	1 Vial
10	6.2.2.9	Metronidazole	Injection 500mg/100mL	0.22	(S.O. 1499(E) dated 30.03.2022)	0.19	1 ML
11	6.2.2.3	Ciprofloxacin	Injection 200mg/100mL	0.19	(S.O. 1499(E) dated 30.03.2022)	0.18	1 ML
12	10.2.2	Amiodarone	Injection 50mg/mL	24.77	(S.O. 1499(E) dated 30.03.2022)	18.85	1 ML
13	10.5.7	Tenecteplase	Injection 40mg/vial	New	New	44939.44	1 Vial
14	10.5.7	Tenecteplase	Injection 30mg/vial	New	New	32917.76	1 Vial
15	7.1.6	Bendamustinehydro chloride	Injection 100 mg/vial	New	New	4411.75	1 Vial
16	6.7.4.4	Lopinavir (A) +Ritonavir(B)	Tablet 200 mg(A)+50mg(B)	50.59	(S.O. 1499(E) dated 30.03.2022)	42.78	1 Tablet
17	6.10.1.1	Artemether (A) +Lumefantrine(B)	Tablet 40 mg (A) + 240 mg (B)	17.92	(S.O. 1499(E) dated 30.03.2022)	16.09	1 Tablet
18	6.8.2	Entecavir	Tablet 0.5mg	88.59	New	75.31	1 Tablet
19	7.2.3	Leuprolideacetate	Powder for injection 22.5 mg	New	New	15233.93	1 Vial
20	7.2.3	Leuprolideacetate	Powder for injection 11.25mg	New	New	8289.17	1 Vial
21	7.2.3	Leuprolideacetate	Powder for injection 3.75 mg	New	New	2776.00	1 Vial
22	6.2.2.1	Azithromycin	Powder for injection 500mg	213.48	(S.O. 1499(E) dated 30.03.2022)	182.58	1 Vial

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Prices with immediate effect	Unit
				Rs./Unit (5)	SO& dated (6)		
(1)	(2)	(3)	(4)			(7)	(8)
23	6.2.2.13	Vancomycin	Powder for injection 500 mg	317.8 3	(S.O. 1499(E) dated 30.03.2022)	283.28	1 Vial
24	6.2.2.13	Vancomycin	Powder for injection 1000mg	528.4 3	(S.O. 1499(E) dated 30.03.2022)	419.40	1 Vial
25	6.6.1.1	Acyclovir	Powder for Injection 250 mg	394.5 2	(S.O. 1499(E) dated 30.03.2022)	380.28	1 Vial
26	22.1.2	Methylergometrine	Tablet 0.125mg	8.79	(S.O. 1499(E) dated 30.03.2022)	7.97	1 Tablet
27	10.5.6	Streptokinase	Injection 15,00,000IU	1987. 53	(S.O. 1499(E) dated 30.03.2022)	1674.28	1 Vial
28	4.2.3	D-Penicillamine	Capsule 250 mg	16.50	(S.O. 1499(E) dated 30.03.2022)	13.96	1 Capsule
29	26.7	Thiamine	Tablet 100 mg	4.16	(S.O. 1499(E) dated 30.03.2022)	3.98	1 Tablet
30	6.2.2.13	Vancomycin	Powder for Injection 250 mg	246.2 1	(S.O. 1499(E) dated 30.03.2022)	224.08	1 Vial
31	7.1.20	Etoposide	Capsule 50mg	60.37	(S.O. 1499(E) dated 30.03.2022)	50.51	1 Capsule
32	10.4.5	Spirolactone	Tablet 50mg	4.22	(S.O. 1499(E) dated 30.03.2022)	3.90	1 Tablet
33	24.1.6	Salbutamol	Oral liquid 2mg/5mL	0.17	(S.O. 1499(E) dated 30.03.2022)	0.16	1 ML
34	17.2.1	Domperidone	Oral Liquid 1mg/mL	1.20	(S.O. 1499(E) dated 30.03.2022)	1.11	1 ML
35	6.2.1.1	Amoxicillin	Capsule 250mg	2.45	(S.O. 1499(E) dated 30.03.2022)	2.18	1 Capsule

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Prices with immediate effect	Unit
				Rs./Unit (5)	SO & dated (6)		
(1)	(2)	(3)	(4)			(7)	(8)
36	6.5.3	Fluconazole	Tablet 150mg	13.15	(S.O. 1499(E) dated 30.03.2022)	10.76	1 Tablet
37	3.2	Cetirizine	Tablet 10mg	1.84	(S.O. 1499(E) dated 30.03.2022)	1.68	1 Tablet
38	5.1.8	Phenobarbitone	Tablet 60mg	1.96	(S.O. 1499(E) dated 30.03.2022)	1.69	1 Tablet
39	6.10.1.3	Artesunate (A) + Sulphadoxine - Pyrimethamine (B)	Combipack (A+B) 1 Tablet 50mg(A) + 1 Tablet (500mg+25mg)(B)	23.56	(S.O. 1499(E) dated 30.03.2022)	20.11	1 CombiP ack
40	10.3.3	Hydrochlorothiazide	Tablet 25 mg	1.87	(S.O. 1499(E) dated 30.03.2022)	1.56	1 Tablet
41	10.1.4	Metoprolol	Modified Release Tablet 100 mg	New	New	13.37	1 Tablet
42	10.1.4	Metoprolol	Tablet 100 mg	New	New	9.93	1 Tablet
43	5.2.1.3	Propranolol	Tablet 20mg	New	New	2.85	1 Tablet
44	6.7.2.1	Efavirenz	Tablet 600mg	78.85	(S.O. 1499(E) dated 30.03.2022)	62.96	1 Tablet
45	6.10.1.4	Chloroquine	Tablet 150 mg	1.32	(S.O. 1499(E) dated 30.03.2022)	1.04	1 Tablet
46	3.6	Prednisolone	Oral liquid 5mg/5mL(p)	0.48	(S.O. 1499(E) dated 30.03.2022)	0.44	1 ML
47	3.6	Prednisolone	Oral liquid 15mg/5mL(p)	0.83	(S.O. 1499(E) dated 30.03.2022)	0.77	1 ML
48	22.1.4	Misoprostol	Tablet 100mcg	9.67	(S.O. 1499(E) dated 30.03.2022)	8.85	1 Tablet

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Prices with immediate effect	Unit
				Rs./Unit (5)	SO& dated (6)		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
49	6.7.1.5	Tenofovir Disproxil Fumarate (A)+Lamivudine(B)	Tablet300mg(A)+300mg(B)	49.84	(S.O. 1499(E) dated 30.03.2022)	40.65	1 Tablet
50	6.7.1.7	Tenofovir Disproxil Fumarate (A) +Lamivudine(B)+Efavirenz(C)	Tablet 300mg(A)+300mg(B)+600mg(C)	114.44	(S.O. 1499(E) dated 30.03.2022)	91.72	1 Tablet
51	6.8.6	Tenofovir DisproxilFumarate(TDF)*	Tablet 300mg	52.39	(S.O. 1499(E) dated 30.03.2022)	40.88	1 Tablet
52	23.2.2.1	Lithium	Tablet 300mg	1.63	(S.O. 1499(E) dated 30.03.2022)	1.45	1 Tablet
53	6.2.1.2	Amoxicillin (A) +Clavulanic acid (B)	Powder for Injection 500mg(A)+100mg(B)	99.96	(S.O. 1499(E) dated 30.03.2022)	90.38	1 Vial
54	6.4.16	Streptomycin	Powder for Injection 750 mg	9.75	(S.O. 1499(E) dated 30.03.2022)	9.01	1 Vial
55	7.1.7	Bleomycin	Powder for injection 15units	689.25	(S.O. 1499(E) dated 30.03.2022)	604.14	1 Vial
56	7.1.14	Cyclophosphamide	Powder for injection 500mg	88.62	(S.O. 1499(E) dated 30.03.2022)	65.54	1 Vial
57	7.1.16	Dacarbazine	Powder for injection 500mg	1100.41	(S.O. 1499(E) dated 30.03.2022)	462.71	1 Vial
58	10.3.3	Hydrochlorothiazide	Tablet 12.5mg	1.10	(S.O. 1499(E) dated 30.03.2022)	0.93	1 Tablet
59	7.3.2	Cyclosporine	Capsule 25 mg	30.55	(S.O. 1499(E) dated 30.03.2022)	25.01	1 Capsule
60	6.6.1.1	Acyclovir	Powder for injection 500 mg	509.56	(S.O. 1499(E) dated 30.03.2022)	471.29	1 Vial
61	23.1.4	Risperidone	Oral liquid	2.15	(S.O. 1499(E)	1.97	1 ML

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Prices with immediate effect	Unit
				Rs./U nit (5)	SO& dated (6)		
(1)	(2)	(3)	(4)			(7)	(8)
			1mg/mL		dated 30.03.2022)		
62	23.1.3	Haloperidol	Oral liquid 2mg/5mL	2.28	(S.O. 1499(E) dated 30.03.2022)	2.00	1 ML
63	20.2	Caffeine	Oral liquid 20 mg/mL	236.7 1	(S.O. 1499(E) dated 30.03.2022)	219.11	1 ML
64	26.4	Cholecalciferol	Oral liquid 400 IU/mL	2.60	(S.O. 1499(E) dated 30.03.2022)	2.33	1 ML
65	7.1.34	Temozolomide	Capsule 100mg	2313. 54	(S.O. 1499(E) dated 30.03.2022)	1345.52	1 Capsule
66	6.10.1.2	Artesunate	Powder for injection 60 mg	242.6 9	(S.O. 1499(E) dated 30.03.2022)	218.26	1 Vial
67	6.10.1.2	Artesunate	Powder for injection 120mg	462.0 4	(S.O. 1499(E) dated 30.03.2022)	405.28	1 Vial
68	7.4.4	Diazepam	Tablet 5 mg	1.58	(S.O. 1499(E) dated 30.03.2022)	1.45	1 Tablet
69	5.1.4	Levetiracetam	Oral liquid 100 mg/mL (p)	4.05	(S.O. 1499(E) dated 30.03.2022)	3.54	1 ML
70	6.1.1.2	Mebendazole	Oral liquid 100mg/5mL(p)	0.85	(S.O. 1499(E) dated 30.03.2022)	0.75	1 ML
71	6.2.1.6	Cefadroxil	Oral liquid 125mg/5mL(p)	0.74	(S.O. 1499(E) dated 30.03.2022)	0.61	1 ML
72	6.2.2.4	Clarithromycin	Oral liquid 125mg/5mL(p)	4.79	(S.O. 1499(E) dated 30.03.2022)	4.11	1 ML
73	6.2.2.9	Metronidazole	Oral liquid 200mg/5mL(p)	0.50	(S.O. 1499(E) dated 30.03.2022)	0.46	1 ML

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Prices with immediate effect	Unit
				Rs./Unit (5)	SO& dated (6)		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
74	6.2.1.2	Amoxicillin (A) +Clavulanic acid (B)	Dry Syrup 125mg(A)+31.25(B)/5mL(p)	2.40	(S.O. 1499(E) dated 30.03.2022)	1.83	1 ML
75	10.5.2	Clopidogrel	Tablet 150 mg	New	New	18.27	1 Tablet
76	18.6.1	Carbimazole	Tablet 20mg	New	New	12.37	1 Tablet
77	6.6.1.1	Acyclovir	Tablet 800mg	New	New	33.59	1 Tablet
78	7.1.2	6-Mercaptopurine	Tablet 50mg	7.17	(S.O. 1499(E) dated 30.03.2022)	4.69	1 Tablet
79	7.3.2	Cyclosporine	Oral liquid 100mg/mL(p)	104.95	(S.O. 1499(E) dated 30.03.2022)	71.87	1 ML
80	10.3.4	Labetalol	Injection 5mg/mL	56.28	(S.O. 1499(E) dated 30.03.2022)	44.58	1 ML
81	1.3.2	Glycopyrrolate	Injection 0.2mg/mL	13.65	(S.O. 1499(E) dated 30.03.2022)	12.96	1 ML
82	8.2.5	Tranexamic acid	Injection 100 mg/mL	16.59	(S.O. 1499(E) dated 30.03.2022)	12.23	1 ML
83	5.1.3	Diazepam	Injection 5mg/mL	6.72	(S.O. 1499(E) dated 30.03.2022)	4.94	1 ML
84	2.1.5	Paracetamol	Oral Liquid 125 mg/5 mL (p)	0.38	(S.O. 1499(E) dated 30.03.2022)	0.33	1 ML
85	7.4.10	Metoclopramide	Oral liquid 5mg/5mL(p)	0.49	(S.O. 1499(E) dated 30.03.2022)	0.45	1 ML
86	4.2.7	Naloxone	Injection 0.4mg/mL	96.32	(S.O. 1499(E) dated 30.03.2022)	82.70	1 ML
87	4.2.9	Pralidoxime chloride(2-PAM)	Injection 25mg/mL	4.14	(S.O. 1499(E) dated 30.03.2022)	4.07	1 ML
88	1.4.3	Neostigmine	Injection	4.83	(S.O. 1499(E) dated 30.03.2022)	4.47	1 ML

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Prices with immediate effect	Unit
				Rs./Unit (5)	SO& dated (6)		
(1)	(2)	(3)	(4)			(7)	(8)
			0.5mg/mL			30.03.2022)	
89	5.1.8	Phenobarbitone	Injection200mg/mL	21.28		(S.O. 1499(E) dated 30.03.2022)	19.75 1 ML
90	7.1.36	Trastuzumab	Injection 440mg/50mL	66790.46		(S.O. 1499(E) dated 30.03.2022)	48806.02 1 Vial
91	7.1.8	Bortezomib	Powder for Injection2mg	13656.22		(S.O. 1499(E) dated 30.03.2022)	4691.51 1 Vial
92	7.1.25	Imatinib	Tablet 400mg	255.28		(S.O. 1499(E) dated 30.03.2022)	178.03 1 Tablet
93	7.1.18	Docetaxel	Powder for injection 80mg	12636.74		(S.O. 1499(E) dated 30.03.2022)	9215.98 1 Vial
94	6.8.3	Ribavirin	Capsule 200 mg	92.88		(S.O. 1499(E) dated 30.03.2022)	23.63 1 Capsule
95	8.2.5	Tranexamic acid	Tablet500 mg	19.28		(S.O. 1499(E) dated 30.03.2022)	16.54 1 Tablet
96	5.3.1	Levodopa (A) +Carbidopa(B)	Modified Release- Tablet200mg(A)+ 50mg(B)	4.56		(S.O. 1499(E) dated 30.03.2022)	4.22 1 Tablet
97	5.2.1.1	Amitriptyline	Tablet 10mg	2.54		(S.O. 1499(E) dated 30.03.2022)	2.13 1 Tablet
98	7.1.28	Lenalidomide	Capsule 25 mg	New	New		260.66 1 Capsule
99	22.1.3	Mifepristone	Tablet 200mg	357.21		(S.O. 1499(E) dated 30.03.2022)	312.96 1 Tablet
100	8.1.4	Folic Acid	Tablet 5 mg	1.55		(S.O. 1499(E) dated 30.03.2022)	1.35 1 Tablet
101	6.3.3	Rifampicin	Capsule 150mg	2.23		(S.O. 1499(E) dated	2.04 1

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Prices with immediate effect	Unit
				Rs./Unit (5)	SO & dated (6)		
(1)	(2)	(3)	(4)			(7)	(8)
					30.03.2022)		Capsule
102	6.3.3	Rifampicin	Capsule 300mg	4.22	(S.O. 1499(E) dated 30.03.2022)	4.11	1 Capsule
103	2.1.3	Ibuprofen	Tablet 400mg	1.15	(S.O. 1499(E) dated 30.03.2022)	1.07	1 Tablet
104	25.1.4	Potassium chloride	Oral liquid 500mg/5mL	0.32	(S.O. 1499(E) dated 30.03.2022)	0.27	1 ML
105	7.4.8	Lactulose	Oral liquid 10 g/15mL	1.22	(S.O. 1499(E) dated 30.03.2022)	1.10	1 ML
106	6.10.1.4	Chloroquine	Oral liquid 50mg/5mL	0.33	(S.O. 1499(E) dated 30.03.2022)	0.30	1 ML
107	5.1.1	Carbamazepine	Oral liquid 100mg/5mL(p)	0.32	(S.O. 1499(E) dated 30.03.2022)	0.28	1 ML
108	18.5.1	Medroxyprogesterone acetate	Injection 150mg/mL	New	New	258.42	1 ML
109	7.1.31	Oxaliplatin	Injection 5 mg/mL in 10 mL vial	2885.84	(S.O. 1499(E) dated 30.03.2022)	1992.32	1 Vial
110	12.1.2	Proparacaine	Eye Drops 0.5%	11.07	(S.O. 1499(E) dated 30.03.2022)	9.14	1 ML
111	2.1.5	Paracetamol	Oral Liquid 250 mg/5 mL (p)	0.66	(S.O. 1499(E) dated 30.03.2022)	0.60	1 ML
112	7.4.14	Ondansetron	Oral liquid 2mg/5mL(p)	1.26	(S.O. 1499(E) dated 30.03.2022)	1.12	1 ML
113	1.3.3	Midazolam	Nasal Spray 1.25mg/actuation	Newly Added	New Added	193.37	1 ML
114	5.1.7	Midazolam	Nasal Spray 0.5 mg/actuation	Newly Added	New Added	71.29	1 ML

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Prices with immediate effect	Unit
				Rs./Unit (5)	SO & dated (6)		
(1)	(2)	(3)	(4)			(7)	(8)
115	7.1.20	Etoposide	Injection 20mg/mL	39.81	(S.O. 1499(E) dated 30.03.2022)	30.78	1 ML
116	12.1.3	Tropicamide	Eye drop 1 %	11.17	(S.O. 1499(E) dated 30.03.2022)	8.41	1 ML
117	21.4.4	Timolol	Drops 0.5 %	13.24	(S.O. 1499(E) dated 30.03.2022)	11.95	1 ML
118	15.3	Mannitol	Injection 20 %	0.33	(S.O. 1499(E) dated 30.03.2022)	0.31	1 ML
119	10.1.2	Glyceryl trinitrate	Injection 5mg/mL	7.29	(S.O. 1499(E) dated 30.03.2022)	5.52	1 ML
120	5.1.9	Phenytoin	Injection 50mg/mL	5.97	(S.O. 1499(E) dated 30.03.2022)	5.31	1 ML
121	2.1.2	Diclofenac	Injection 25mg/mL	1.63	(S.O. 1499(E) dated 30.03.2022)	1.51	1 ML
122	4.2.6	N-acetylcysteine	Injection 200 mg/mL	24.88	(S.O. 1499(E) dated 30.03.2022)	21.08	1 ML
123	10.4.3	Dopamine	Injection 40mg/mL	6.27	(S.O. 1499(E) dated 30.03.2022)	4.25	1 ML
124	6.4.16	Streptomycin	Powder for injection 1000mg	11.59	(S.O. 1499(E) dated 30.03.2022)	9.69	1 Vial
125	2.1.5	Paracetamol	Oral liquid 120 mg/5 mL (p)	0.59	(S.O. 1499(E) dated 30.03.2022)	0.54	1 ML
126	18.4.1	Clomiphenecitrate	Tablet 100 mg	13.57	(S.O. 1499(E) dated 30.03.2022)	12.44	1 Tablet
127	18.4.1	Clomiphenecitrate	Tablet 50mg	9.24	(S.O. 1499(E) dated 30.03.2022)	7.88	1 Tablet

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Prices with immediate effect	Unit
				Rs./Unit (5)	SO& dated (6)		
(1)	(2)	(3)	(4)			(7)	(8)
128	18.5.1	Medroxyprogesterone acetate	Tablet 10 mg	5.98	(S.O. 1499(E) dated 30.03.2022)	5.57	1 Tablet

7. Agenda item no. 7 -Form-IV intimation for discontinuation of 4 scheduled formulations viz., (i) Urografin 76%-20ml (ii) Urografin 76%-50ml (iii) Urografin 76%-100ml (iv) Urografin 60%-20ml by M/s Bayer Zydus Pharma under para 21(2) of DPCO, 2013-reg.

7.1 The Authority noted that the company has already been directed to continue import/ production and sale up to 17.02.2023 and to ensure the production is not reduced by more than 25% of last year's production in view of its majority market share for all the four formulations. The Authority also noted the recommendations of the 8th meeting of the Committee on Discontinuation held on 6th December 2022 to invoke Para 3 in the matter for further 1 year considering the substantial market share of the formulation and larger public interest.

7.2 The Authority deliberated upon the matter in detail and decided to invoke Para 3 of DPCO, 2013 to direct M/s Bayer Zydus Pharma to continue the production and sales of the subject scheduled formulations (i) Urografin 76%-20ml (ii) Urografin 76%-50ml (iii) Urografin 76%-100ml and (iv) Urografin 60%-20ml up to 29.02.2024 and to ensure the production is not reduced by more than 25% of last year's production.

8. Agenda item no. 8-Request of M/s Meril Life Sciences Pvt. Ltd. For extension of exemption granted under Para 32 (ii) of DPCO, 2013 by one year beyond 5 years.

8.1 The request of M/s Meril Life Sciences Pvt. Ltd, for extension of period of exemption granted under Para 32 (ii) of DPCO, 2013 by one year in respect of the drug, Coronary Stent namely "Sirolimus Eluting BioResorbable Vascular Scaffold System (MeRes100) and the reasons given for the same were discussed by the Authority.

8.2 The matter was discussed in the Authority in detail and it was noted that Para 32(ii) grants exemption from applicability of provisions of DPCO, 2013 to a manufacturer producing a new drug in the country by a new process developed through indigenous Research and Development and patented under the Indian Patent Act, 1970(39 of 1970) for a period of five years from the date of the commencement of its commercial production in the country. However, it was noted by the Authority that DPCO, 2013 does

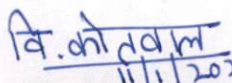
not provide for extension of the exemption period. Accordingly, the request of the company was not accepted.

9. Agenda item no. 9 -Methodology for calculation of interest in Demand Notices to be issued under Drugs (Price Control) Order, 2013 for recovery of Overcharged amount.

9.1 The Authority deliberated upon the matter in detail including the Committee Report dated 27.12.2022 on the subject matter. The existing methodology is an established practice of calculation of interest on the Overcharged (OC) amount. The same methodology was being followed by the Drug Price Liability Review Committee (DPLRC) and Department of Pharma (DoP) for calculation of interest under DPCO, 1979, DPCO, 1987 and DPCO, 1995. After the constitution of the NPPA in 1997, NPPA also adopted this methodology and continued with it while implementing provision of DPCO 1995 and DPCO 2013. It was also informed to the Authority that the DPCO, 2013 and Essential Commodity Act, 1955 provides for charging of simple interest.

9.2 After detailed discussions, the Authority decided to continue with the current methodology of calculation of interest in Demand Notices to be issued under Drugs (Price Control) Order, 2013 for recovery of overcharged amount. Further, the Authority also directed to examine the methodology being followed under the other orders issued under the EC Act, 1955, wherein the amount overcharged by the companies from the consumers are recovered, for future references.

The meeting ended with a vote of thanks to the Chair and all the participants in the meeting.


11/1/2023
(Dr. Vinod Kotwal)
Member Secretary