

मिसिलस.- 8(108)/2023/डी.पी/एनपीपीए-डीवी-II
F. No. 8(108)/2023/DP/NPPA-Div. II

कार्यवाहीस. : 240/108/2023/F
Proceeding No: 240/108/2023/F

Minutes of the 240th (overall) and 108th meeting of the Authority under DPCO, 2013 held on 27.01.2023 at 3:30PM.

The 240th meeting of the Authority (overall), which is the 108th meeting under the DPCO, 2013, was held on 27th January, 2023 at 03:30PM 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 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) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (v) Shri Mahaveer Saini, Deputy Director (Pricing)
- (vi) Ms. Yuvika Panwar, Assistant Director (Overcharging /Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 107th Meeting held on 11.01.2023.

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 107th Meeting held on 11.01.2023.

2.1 Noted.

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

3.1 Noted.

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

It.

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (xvii) (total 17 Form I applications containing retail price fixation of 17 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 17(Seventeen) 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)	Rosuvastatin and Clopidogrel Capsule	Each Hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (As Pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Zydus Healthcare Limited	19.04
4 (ii)	Domperidone and Naproxen Sodium Tablets	Each film coated tablet contains: Domperidone Maleate IP eq. to Domperidone 10mg Naproxen Sodium USP 550mg eq. to Naproxen 500mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	6.99
4 (iii)	Domperidone and Naproxen Sodium Tablets	Each film coated tablet contains: Domperidone Maleate IP eq. to Domperidone 10mg Naproxen Sodium USP 275mg eq. to Naproxen 250mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	5.39
4 (iv)	Rosuvastatin, Clopidogrel & Aspirin Capsule	Each Hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 75mg	1 Capsule	M/s Windlas Biotech Limited. / M/s Modi-Mundipharma Pvt. Ltd.	14.48
4 (v)	Calcium, Phosphorus, Magnesium, Zinc & Vitamin D3 Suspension	Each 10ml contains: Calcium Phosphate IP eq. to Elemental Calcium 300mg eq. to Elemental Phosphorus 150mg Magnesium Hydroxide IP eq. to Elemental Magnesium 75mg Zinc Gluconate USP eq. to Elemental Zinc 4mg Vitamin D3 IP 200IU	1 ml	M/s Pharma Force Lab. / M/s Mankind Pharma Ltd.	0.68
4 (vi)	Phenylephrine Hydrochloride, Chlorpheniramine Maleate,	Each 5ml contains: Phenylephrine Hydrochloride IP 5mg Chlorpheniramine Maleate	1 ml	M/s Bioconic Remedies / M/s Dales Laboratories Pvt. Ltd.	0.87

Handwritten mark

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Paracetamol, Sodium Citrate & Menthol Suspension	IP 0.5mg Paracetamol IP 125mg Sodium Citrate IP 60mg Menthol IP 1mg			
4 (vii)	Methylcobalamin, Alpha Lipoic Acid, Inositol, Folic Acid, Chromium Polynicotinate, Selenium Dioxide & Benfotiamine Capsule	Each soft Gelatin Capsule contains: Methylcobalamin IP 1500mcg Alpha Lipoic Acid USP 100mg Inositol USP NF 100mg Folic Acid IP 1.5mg Chromium Polynicotinate 200mcg Selenium Dioxide USP 55mcg Benfotiamine 150mg	1 Capsule	M/s Olive Healthcare / M/s Intas Pharmaceuticals Limited	18.56
4 (viii)	Itraconazole Capsule (Supra-Bioavailable Formulation)	Each hard gelatin capsule contains: Itraconazole BP 65mg	1 Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s IPCA Laboratories Limited	11.6
4 (ix)	Itraconazole Capsule (Supra-Bioavailable Formulation)	Each hard gelatin capsule contains: Itraconazole BP 130mg	1 Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s IPCA Laboratories Limited	20.72
4 (x)	Rosuvastatin, Aspirin and Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (as film coated tablet) Aspirin IP 75mg (As Gastro-resistant tablet) Clopidogrel Bisulphate eq. to Clopidogrel IP 75 mg (as film coated tablet)	1 Capsule	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	14.48
4 (xi)	Rosuvastatin, Aspirin and Clopidogrel Capsule	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (as film coated tablet) Aspirin IP 75mg (As Gastro-resistant tablet) Clopidogrel Bisulphate eq. to Clopidogrel IP 75 mg (as film coated tablet)	1 Capsule	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Ltd.	20.69
4 (xii)	Ferrous Ascorbate, Folic Acid & Methylcobalamin Suspension	Each 5ml contains: Ferrous Ascorbate IP eq. to Elemental Iron 30mg Folic Acid IP 500mg Methylcobalamin IP 500mcg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Limited	0.92
4 (xiii)	Doxorubicin Hydrochloride Liposomal	Each ml Contains: Doxorubicin Hydrochloride IP 2mg (as Pegylated	1 ml	M/s Samarth Life Sciences Pvt. Ltd.	452.45

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Injection (Pegylated liposomal)	liposomal) water for injection			
4 (xiv)	Diclofenac Sodium & Dicyclomine Hydrochloride Injection	Each ml contains: Diclofenac Sodium IP 50mg Dicyclomine Hydrochloride IP 20mg Benzalkonium Chloride Solution IP 0.05% w/v Water for Injections q. s.	1 ml	M/s Nichepharm Lifesciences Pvt. Ltd. / M/s Seagull Pharmaceuticals Pvt, Ltd.	31.08
4 (xv)	Paracetamol & Mefenamic Acid Suspension	Each 5ml contains: Paracetamol IP 250mg Mefenamic Acid IP 100mg	1 ml	M/s Prosperity Drugs Pvt. Ltd. / M/s Torrent Pharmaceuticals Limited	0.75
4 (xvi)	Paracetamol & Mefenamic Acid Suspension	Each 5ml contains: Paracetamol IP 125mg Mefenamic Acid IP 50mg	1 ml	M/s Prosperity Drugs Pvt. Ltd. / M/s Torrent Pharmaceuticals Limited	0.65
4 (xvii)	Cefixime and Potassium Clavulanate Tablets IP	Each film coated tablet contains: Cefixime Trihydrate eq. to Cefixime Anhydrous IP 200mg Potassium Clavulanate Diluted eq. to Clavulanic Acid IP 125mg	1 Tablet	M/s Alps Communications Pvt. Ltd. / M/s Aristo Laboratories Pvt. Ltd.	24.00

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 the Authority held on 23.11.2022. Based on the approved methodology, ceiling prices for formulations are uploaded on the 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. The details of draft working sheets uploaded are given in **Table 2**.



Table No. 2: Status of draft working sheets uploaded on the NPPA website

S.No	Date of upload of draft working sheets	10 days completed on	No. of formulations uploaded	Approved in earlier meetings	No. of formulations proposed for approval in current meeting
1.	25.11.2022	09.12.2022	121	119	-
2.	01.12.2022	15.12.2022	43	34	6
3.	02.12.2022	16.12.2022	51	46	4
4.	05.12.2022	19.12.2022	15	14	1
5.	13.12.2022	27.12.2022	69	67	1
6.	20.12.2022	03.01.2023	30	30	-
7.	23.12.2022	06.01.2023	35	34	-
8.	06.01.2023	20.01.2023	45	-	43
	Total		409	344	55

6.2 The Authority was apprised that total 792 representations have been received till 20.01.2023 from companies within the prescribed time lines of 10 days. Companies have submitted copy of invoice(s) showing the revised PTR and snapshots of sample pack showing revised MRP. The representations are broadly related to:

(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.
- ii. The representation dated 13.01.2023 was received from M/s Johnson & Johnson Private Ltd for the formulation Risperidone Long Acting Injection 25 mg/ml. NPPA had uploaded the draft working sheet for the above formulation on 06.01.2023 where two line items, RESTONORM by M/s Aleteus Biogenics Ltd and RISPERDAL CONSTA by M/s Johnson & Johnson Private Ltd were considered for calculation. The company M/s Johnson & Johnson Private Ltd has represented that the brand RESTONORM is manufactured by M/s HFA Formulations Pvt ltd, and CDSCO has not received the application from M/s HFA Formulations Pvt ltd for manufacturing of Risperidone Long Acting Injection 25 mg/ml.

6.3. The Authority deliberated upon the matter of representation dated 13.01.2023 received from M/s Johnson & Johnson Private Ltd and directed that clarification may be sought from DCGI with respect to the approval status of RESTONORM marketed by M/s Aleteus Biogenics Ltd and manufactured by M/s HFA Formulations Pvt ltd. Accordingly,

the ceiling price proposed for one of the formulation i. e Risperidone Injection (long acting) 25 mg was deferred by the Authority.

6.4 Authority noted that there was price revision in 33 formulations as compared to the ceiling prices reflected in the draft uploaded working sheets. The Authority deliberated and approved the ceiling prices of 54 formulations as appearing in column (7) of the Table 3.

Table 3: Ceiling Prices of 55 formulations

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Price	Unit
				(Rs. /Unit)	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1	17.1.1	Omeprazole	Capsule20 mg	2.77	(S.O. 1499(E) dated 30.03.2022)	2.56	1 Capsule
2	2.3.2	Colchicine	Tablet0.5mg	3.46	(S.O. 1499(E) dated 30.03.2022)	2.91	1 Tablet
3	6.2.1.1	Amoxicillin	Capsule500mg	7.17	(S.O. 1499(E) dated 30.03.2022)	6.56	1 Capsule
4	3.3	Dexamethasone	Tablet0.5mg	0.21	(S.O. 1499(E) dated 30.03.2022)	0.2	1 Tablet
5	3.6	Prednisolone	Tablet10mg	1.09	(S.O. 1499(E) dated 30.03.2022)	1.07	1 Tablet
6	18.1.5	Prednisolone	Tablet5mg	0.62	(S.O. 1499(E) dated 30.03.2022)	0.61	1 Tablet
7	6.2.2.1	Azithromycin	Tablet250mg	11.72	(S.O. 1499(E) dated 30.03.2022)	10.39	1 Tablet
8	6.2.2.1	Azithromycin	Tablet500mg	23.64	(S.O. 1499(E) dated 30.03.2022)	21.02	1 Tablet
9	3.6	Prednisolone	Tablet20mg	2.17	(S.O. 1499(E) dated 30.03.2022)	2.14	1 Tablet
10	6.10.2.1	Doxycycline	Capsule100mg	2.78	(S.O. 1499(E) dated 30.03.2022)	2.75	1 Capsule
11	2.1.5	Paracetamol	Tablet500mg	1.01	(S.O. 1499(E) dated 30.03.2022)	0.8	1 Tablet
12	5.1.10	SodiumValproate	Oralliquid200mg /5mL(p)	0.64	(S.O. 1499(E) dated 30.03.2022)	0.58	1 ML
13	26.4	Cholecalciferol	Solid oral dosage form 60000 IU Tablets	26.93	(S.O. 1499(E) dated 30.03.2022)	20.07	1 Tablet
14	7.1.2.1	Gefitinib	Tablet250mg	475.9	(S.O. 1499(E) dated 30.03.2022)	211.49	1 Tablet
15	7.3.3	Mycophenolate mofetil	Tablet250mg	46.1	(S.O. 1499(E) dated 30.03.2022)	44.24	1 Tablet
16	6.2.1.10	Ceftazidime	Powder for Injection 250 mg	72.27	(S.O. 1499(E) dated 30.03.2022)	70.52	1 Vial
17	16.4	Xylometazoline	Nasal drops 0.05 %	4.36	(S.O. 1499(E) dated 30.03.2022)	3.74	1 ML
18	16.4	Xylometazoline	Nasaldrops0.1%	5.78	(S.O. 1499(E) dated 30.03.2022)	4.57	1 ML
19	17.5.1	Bisacodyl	Suppository5mg	9.37	(S.O. 1499(E) dated 30.03.2022)	8.9	1 Supposito

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Price	Unit
				(Rs. /Unit)	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
					30.03.2022)		ry
20	5.1.4	Levetiracetam	Injection100mg/mL	24.22	(S.O. 1499(E) dated 30.03.2022)	20.53	1 ML
21	7.4.14	Ondansetron	Injection2mg/mL	6.49	(S.O. 1499(E) dated 30.03.2022)	5.32	1 ML
22	6.5.3	Fluconazole	Tablet50mg	New Added	New Added	8.63	1 Tablet
23	2.1.5	Paracetamol	Suppository80mg	7.22	(S.O. 1499(E) dated 30.03.2022)	5.94	1 Suppository
24	2.1.5	Paracetamol	Suppository170mg	8.54	(S.O. 1499(E) dated 30.03.2022)	7.09	1 Suppository
25	22.1.2	Methylergometrine	Injection0.2mg/mL	15.85	(S.O. 1499(E) dated 30.03.2022)	13.33	1 ML
26	7.1.15	Cytosinearaboside	Injection100mg/vial	220.59	(S.O. 1499(E) dated 30.03.2022)	124.49	1 Vial
27	7.1.15	Cytosinearaboside	Injection500mg/vial	568.66	(S.O. 1499(E) dated 30.03.2022)	478.32	1 Vial
28	1.1.3	Ketamine	Injection50mg/mL	11.61	(S.O. 1499(E) dated 30.03.2022)	10.81	1 ML
29	7.1.38	Vincristine	Injection1mg/mL	57.86	(S.O. 1499(E) dated 30.03.2022)	51.3	1 ML
30	2.2.3	Tramadol	Injection50mg/mL (upto 2ml pack)	11.63	(S.O. 1499(E) dated 30.03.2022)	10.51	1 ML
31	22.1.5	Oxytocin	Injection5 IU/mL	19.59	(S.O. 1499(E) dated 30.03.2022)	15.91	1 ML
32	23.1.4	Risperidone	Injection(Longacting)25mg		Deferred		
33	6.2.2.1	Azithromycin	Oral liquid 200 mg/5 mL (p)	3.42	(S.O. 1499(E) dated 30.03.2022)	3.04	1 ML
34	3.2	Cetirizine	Oral liquid 5mg/5 mL(p)	0.65	(S.O. 1499(E) dated 30.03.2022)	0.59	1 ML
35	6.2.1.2	Amoxicillin (A) +Clavulanicacid (B)	Oral liquid 200 mg (A) + 28.5mg(B)/5 mL(p)	2	(S.O. 1499(E) dated 30.03.2022)	1.8	1 ML
36	6.2.1.8	Cefixime	Oral liquid 50 mg/5 mL (p)	1.62	(S.O. 1499(E) dated 30.03.2022)	1.45	1 ML
37	6.2.1.8	Cefixime	Oral liquid 100mg /5mL(p)	2.39	(S.O. 1499(E) dated 30.03.2022)	2.13	1 ML
38	7.1.33	Rituximab	Injection10mg/mL	842.18	(S.O. 1499(E) dated 30.03.2022)	679.41	1 ML
39	25.1.6	Sodium bicarbonate	Injection (as per IP) - 8.4%	1.43	(S.O. 1499(E) dated 30.03.2022)	1.2	1 ML
40	6.10.1.6	Primaquine	Tablet15mg	5.07	(S.O. 1499(E) dated 30.03.2022)	4.58	1 Tablet
41	6.7.4.5	Ritonavir	Tablet100mg	32.23	(S.O. 1499(E) dated 30.03.2022)	26.05	1 Tablet
42	5.1.1	Carbamazepine	Tablet100mg	1.13	(S.O. 1499(E) dated 30.03.2022)	0.95	1 Tablet
43	2.1.3	Ibuprofen	Oral liquid 100mg /5mL(p)	0.21	(S.O. 1499(E) dated 30.03.2022)	0.2	1 ML

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price		New Ceiling Price	Unit
				(Rs. /Unit)	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
					30.03.2022)		
44	6.7.1.10	Zidovudine (A) +Lamivudine (B) +Nevirapine (C)	Tablet300mg(A) +150mg(B)+200 mg (c)	22.37	(S.O. 1499(E) dated 30.03.2022)	18.85	1 Tablet
45	10.4.5	Spironolactone	Tablet25mg	2.13	(S.O. 1499(E) dated 30.03.2022)	1.95	1 Tablet
46	15.1	Furosemide	Tablet40mg	0.83	(S.O. 1499(E) dated 30.03.2022)	0.81	1 Tablet
47	10.2.6	Verapamil	Tablet 80 mg	1.55	(S.O. 1499(E) dated 30.03.2022)	1.42	1 Tablet
48	10.2.6	Verapamil	Tablet40mg	0.82	(S.O. 1499(E) dated 30.03.2022)	0.77	1 Tablet
49	21.1.3	Natamycin	Drops 5%	25.32	(S.O. 1499(E) dated 30.03.2022)	20.85	1 ML
50	21.5.2	Homatropine	Drops 2%	6.89	(S.O. 1499(E) dated 30.03.2022)	5.71	1 ML
51	21.6.1	Carboxymethyl cellulose	Drops0.5%	14.49	(S.O. 1499(E) dated 30.03.2022)	10.97	1 ML
52	21.6.1	Carboxymethyl cellulose	Drops 1%	19.66	(S.O. 1499(E) dated 30.03.2022)	14.79	1 ML
53	24.1.6	Salbutamol	Inhalation (MDI/DPI*) 100mcg/dose	0.44	(S.O. 1499(E) dated 30.03.2022)	0.44	1 MDI
54	24.1.6	Salbutamol	RespiratorSoluti on (SolutionforNeb ulizer5mg/mL)	0.78	(S.O. 1499(E) dated 30.03.2022)	0.61	1 ML
55	26.5	Pyridoxine	Tablet100 mg	6.2	(S.O. 1499(E) dated 30.03.2022)	5.33	1 Tablet

Separate Ceiling Prices for drugs with special features:

6.5 The Authority noted that based on the recommendation of MDC in its 35th Meeting held on 18.08.2021, separate ceiling prices were approved by the Authority in its 92nd meeting for three companies i.e. M/s Otsuka Pharmaceuticals Pvt. Limited, M/s Denis Chem Lab Ltd. and M/s Rusoma Laboratories Pvt. Ltd. for the following two formulations by adding 15% over the normal ceiling prices for having the special features. Their prevailing ceiling prices under NLEM 2015 are as given below in Table 4:

Table 4: Ceiling prices fixed for three companies for two formulations

S.No.	Formulation	Normal Ceiling Price under NLEM 2015 (Rs./Unit)	Separate Ceiling Price for drugs with Special features under NLEM 2015 fixed vide SO No. 1505 & 1504 dated 30.03.2022 (Rs./Unit)
1	Mannitol Injection 20%	Rs. 0.33/ML	Rs.0.382/ML
2	Metronidazole Injection 500mg/100ml	Rs. 0.22/ML	Rs. 0.25 /ML

72

6.6 As the prices of above two formulations have been refixed under NLEM 2022 in the 107th meeting, the Authority deliberated upon the matter and approved the following ceiling prices for M/s Otsuka Pharmaceuticals Pvt. Limited, M/s Denis Chem Lab Ltd. and M/s Rusoma Laboratories Pvt. Ltd. for following two formulations by adding 15% over the ceiling prices refixed under NLEM 2022 on account of the special features, as given below in Table 5:

Table 5: Ceiling Price on account of special features

S.No.	Formulation	Normal Ceiling Price under NLEM 2022 (Rs./Unit)	Notification No.	Separate Ceiling Price (Rs./Unit) by adding @15%
1	Mannitol Injection 20%	Rs. 0.31/ML	S.O. 194(E) (11.01.2023)	Rs. 0.36/ML
2	Metronidazole Inejction 500mg/100ml	Rs. 0.19/ML	S.O. 194(E) (11.01.2023)	Rs. 0.22/ML

6.7 The authority also noted that if any company other than these, intends to launch the said formulations with special feature as mentioned above, it shall apply to NPPA for separate ceiling price.

Agenda Item 7: Ceiling Price fixation of new formulations included in NLEM 2022 with interbrand price variation in various brands of one company exceeding 10%.

7.1 The Authority deliberated upon the matter of the formulations included in the NLEM 2022 for the first time and consequently, such non-scheduled formulations becoming schedule formulations. During the deliberations, large interbrand variation in the prices in some of the formulations of the same company was brought to the notice of Authority.

7.2 After deliberations, the Authority decided to address the interbrand price variation while fixing the prices of the formulations that have been included under NLEM 2022 for the first time. Accordingly, the Authority decided that Price to Retailer (PTR) of various brands/ pack sizes of a formulation of a one company may be capped at price of the lowest brand/ pack size plus 10%, based on an existing reference under DPCO 2013. It is also decided that the price of such formulations may be fixed under Para 19 of DPCO 2013 in public interest.

7.3 The annual price increase on such formulations may be allowed as per para16 of DPCO, 2013 on the basis of WPI similar to other schedule formulations for which price is fixed under Para 4 and 6 of DPCO 2013.

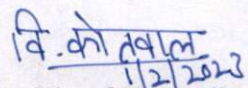
Agenda Item 8: Retail price fixation under Para 5 of DPCO, 2013- Each uncoated tablet containing Diclofenac Sodium IP 50 mg + Paracetamol IP 325 mg for M/s Akums Drugs & Pharmaceuticals Ltd. (manufacturer) and M/s Emcure Pharmaceuticals Ltd. (marketers)

8.1 The Authority deliberated upon the matter in detail and decided that since M/s Akums Drugs & Pharmaceuticals Ltd. is an existing manufacturer of new drug, the retail price may be fixed by NPPA. Accordingly, the Authority approved the retail price of Rs. 4.20 per tablet (excluding GST) for each uncoated tablet containing Diclofenac Sodium IP 50 mg + Paracetamol IP 325 mg for M/s Akums Drugs & Pharmaceuticals Ltd. (manufacturer) and M/s Emcure Pharmaceuticals Ltd. (marketers).

Agenda Item 9: Form-IV Intimation by M/s Neon Laboratories Limited in respect of scheduled formulation Tropine 1ml Injection (Atropine Sulphate Injection 0.6mg/ml) under para 21(2) of DPCO, 2013

9.1 The Authority deliberated upon the matter in detail and decided to re-invoke Para 3 of DPCO 2013 in public interest since M/s Neon Laboratories Limited is having substantial market share of in respect of scheduled formulation Tropine 1ml Injection (Atropine Sulphate Injection 0.6mg/ml). The Authority decided that the company, M/s Neon Laboratories Limited shall be directed to maintain the production and sales of Tropine 1ml Injection (Atropine Sulphate Injection 0.6mg/ml) at current level beyond 05.02.2023 for a period of one year i.e. up to 29.02.2024

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


(Dr. Vinod Kotwal)
Member Secretary