

मिसिलस.- 8(118)/2023/डी.पी/एनपीपीए-डीवी-II
F. No. 8(118)/2023/DP/NPPA-Div. II

कार्यवाहीस. : 250/118/2023/F
Proceeding No: 250/118/2023/F

Minutes of the 250th(overall) and 118thmeeting of the Authority under DPCO, 2013 held on 08.11.2023 at 11:00 AM.

The 250th meeting of the Authority (overall) which is the 118th meeting under the DPCO, 2013 was held on 8th November, 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 Antony Cyriac, Economic Advisor, Department of Economic Affairs

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

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

- (i) Shri Sanjay Kumar, Advisor (Cost-I)
- (ii) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (iii) Shri Mahaveer Saini, Deputy Director (Pricing)
- (iv) Ms. Yuvika Panwar, Assistant Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 117th Meeting held on 13.10.2023.

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 117th Meeting held on 13.10.2023.

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

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (xxxi) (total 33 Form I applications containing retail price fixation of 33 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 33 (thirty-three) new drugs under Para 5 and 15 of the DPCO 2013, as detailed in **Table 1** below:

Table No. 1: Retail price fixation of new drugs

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (i)	Metoprolol Succinate Extended Release, Cilnidipine & Telmisartan Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (As Extended release) Telmisartan IP 40mg, Cilnidipine IP 10mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	10.04
4 (ii)	Amoxicillin + Potassium Clavulanate Oral Suspension	Each combi pack contains: (A) Amoxicillin and Potassium Clavulanate Oral Suspension IP Each 5ml of Reconstituted suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 57mg (B) Sterile water for Reconstitution-30 ml	1 ml	M/s Malik Life Sciences Pvt. Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	4.16
4 (iii)	Vildagliptin + Metformin Hydrochloride Tablet	Each film coated tablet contains: Vildagliptin IP 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	8.32

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (iv)	Vildagliptin + Metformin Hydrochloride Tablet	Each film coated tablet contains: Vildagliptin IP 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	7.89
4 (v)	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated tablet contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	9.62
4 (vi)	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated tablet contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	11.31
4 (vii)	Metoprolol Succinate Extended Release, Cilnidipine & Telmisartan Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended release) Telmisartan IP 40mg, Cilnidipine IP 10mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	12.46
4 (viii)	Atorvastatin & Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg Ezetimibe IP 10mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Eris Lifesciences Limited	23.85
4 (ix)	Atorvastatin & Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 40mg Ezetimibe IP 10mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Eris Lifesciences Limited	32.61
4 (x)	Cholecalciferol (Vitamin D3) Oral Solution 60000IU	Each 5ml Syrup contains: Cholecalciferol 60000 IU	1 ml	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Zuventus Healthcare Limited	12.27
4 (xi)	Telmisartan and	Each film coated	1	M/s Pure and	11.96

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Metoprolol Succinate (ER) Tablet	bilayered tablet contains: Telmisartan IP 40mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (as extended release form)	Tablet	Cure Healthcare Pvt. Ltd. / M/s La Renon Healthcare Pvt. Ltd.	
4 (xii)	Ceftriaxone & Sulbactam for Injection	Each vial contains: Sterile Ceftriaxone Sodium IP eq. to Ceftriaxone 1000mg Sterile Sulbactam Sodium IP eq. to Sulbactam 500mg	1 vial	M/s Scott-Edil Advance Research Laboratories and Education Ltd. / M/s J.B. Chemicals & Pharmaceuticals Ltd.	142.48
4 (xiii)	Bisoprolol Fumarate & Amlodipine tablet	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	6.19
4 (xiv)	Bisoprolol Fumarate & Amlodipine tablet	Each film coated tablet contains: Bisoprolol Fumarate IP 5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	8.34
4 (xv)	Amoxicillin & Potassium Clavulanate Oral Suspension IP	Each 5ml (after reconstitution) contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg Potassium Clavulanate diluted IP eq. to Clavulanic Acid 57mg	1 ml	M/s Uni Medicolabs / M/s Torrent Pharmaceuticals Ltd.	4.20
4 (xvi)	Diclofenac Diethylamine, Methyl Salicylate, Menthol & Virgin Linseed Oil	Composition : Diclofenac Diethylamine IP 1.16%w/w eq. to Diclofenac Sodium IP 1% w/w	1 Gram	M/s Pontika Aerotech Limited / M/s Blue Cross Laboratories Pvt. Ltd.	2.83

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Topical Spray	Virgin Linseed Oil BP 3% w/w Methyl Salicylate IP 10% w/w Menthol IP 5%w/w			
4 (xvii)	Rabeprazole Sodium and Domperidone SR Capsules	Each hard gelatin capsule contains: Rabeprazole Sodium IP 20mg (As enteric coated pellets) Domperidone IP 30mg (as Sustained release pellets)	1 Capsule	M/s Aagya Biotech Pvt. Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	11.52
4 (xviii)	Metronidazole, Lignocaine Hydrochloride and Chlorhexidine Gluconate Gel	Contains: Metronidazole Benzoate IP eq. to Metronidazole 1% w/w Lignocaine Hydrochloride IP 2% w/w Chlorhexidine Gluconate Solution IP eq. to Chlorhexidine Gluconate 1% w/w	1 Gram	M/s J.B. Chemicals & Pharmaceuticals Ltd.	4.22 (Note 1)
4 (xix)	Rosuvastatin + Clopidogrel Capsules	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 Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	19.21
4 (xx)	Rosuvastatin + Clopidogrel Capsules	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 Skymap Pharmaceuticals Pvt. Ltd.	19.21
4 (xxi)	Rosuvastatin + Clopidogrel Capsules	Each hard gelatin capsule contains: Rosuvastatin Calcium IP eq. to Rosuvastatin	1 Capsule	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Jagsonpal	19.21

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		20mg (as Pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (as Pellets)		Pharmaceutica ls Ltd.	
4 (xxii)	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated tablet contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Zydus Healthcare Ltd.	11.36
4 (xxiii)	Telmisartan and Bisoprolol Fumarate Tablets	Each film coated tablet contains: Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Zydus Healthcare Ltd.	9.69
4 (xxiv)	Hydroxychloroq uine Sulphate tablet	Each film coated tablet contains: Hydroxychloroquine Sulphate IP 300mg	1 Tablet	M/s Innova Captab Ltd. / M/s Brinton Pharmaceutica ls Limited	13.54
4 (xxv)	Ibuprofen Injection	Each ml contains: Ibuprofen IP 100mg	1 ml	M/s Akums Drugs & Pharmaceutica ls Ltd. / M/s Cipla Ltd.	26.78
4 (xxvi)	Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramin e maleate, Ammonium Chloride, Sodium Citrate & Menthol Suspension	Each 5ml contains: Paracetamol IP 250mg Phenylephrine Hydrochloride IP 5mg Chlorpheniramine maleate IP 2mg Ammonium Chloride IP 120mg Sodium Citrate IP 60mg Menthol IP 1mg	1 ml	M/s Windlas Biotech Limited / M/s Intas Pharmaceutica ls Ltd.	0.82
4 (xxvii) a	Sitagliptin Phosphate, Metformin Hydrochloride and Glimpiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Sun Pharma Laboratories Limited	13.10

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Glimepiride IP 1 mg			
4 (xxvii) b	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Sun Pharma Laboratories Limited	14.60
4 (xxviii) a	Linagliptin + Metformin Hydrochloride (ER) Tablet	Each film coated bilayered tablet contains: Linagliptin 5mg Metformin Hydrochloride (as Extended release) IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	14.37
4 (xxix)	Budesonide, Glycopyrronium & Formoterol Fumarate Dihydrate Inhaler	Each actuation delivers: Budesonide IP 200mcg Glycopyrronium (as Glycopyrrolate IP) 12.5mcg Formoterol Fumarate Dihydrate suspended in propellant IP 6mcg	Per pack of 120 MDI	M/s Cipla Limited	855.00
4 (xxx) a	Insulin Glargine 100IU /ml and Lixisenatide 50mcg/ml	Each prefilled pen containing: Fixed Ratio combination of Insulin Glargine 100IU /ml Lixisenatide 50mcg/ml	1ml	M/s Sanofi Healthcare India Pvt. Ltd. / M/s Sanofi India Limited	587.30
4 (xxx) b	Insulin Glargine 100IU /ml and Lixisenatide 33mcg/m	Each prefilled pen containing: Fixed Ratio combination of Insulin Glargine 100IU /ml Lixisenatide 33mcg/ml	1ml	M/s Sanofi Healthcare India Pvt. Ltd. / M/s Sanofi India Limited	587.30
4 (xxxi)	Combikit of Atazanavir +	Each Combikit contains:	1 Combi	M/s Emcure Pharmaceuticals	112.60

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Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Ritonavir & Emtricitabine + Tenofovir Alafenamide Tablet	Part A: Each film coated tablet contains: Atazanavir Sulphate IP eq. to Atazanavir 300mg Ritonavir IP 100mg Part B: Each film coated tablet contains: Emtricitabine IP 200mg Tenofovir Alafenamide Fumarate eq. to Tenofovir Alafenamide 10mg	Kit	Is Limited	

Note 1: The Authority noted the representation received from M/s J.B. Chemicals & Pharmaceuticals Ltd for correction in PTR of one of line items considered in the uploaded draft worksheet. However, the same was not considered as the revision in PTR as contended by M/S J.B. Chemicals & Pharmaceuticals Ltd was done in April 2023, whereas the PTR for price fixation for the said formulation mentioned at Sr. No.4 (xviii) has been considered for the month of March 2023 i.e. 6 months prior to the data of application. Hence, the Authority decided that no change is required in the draft work sheet uploaded.

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

5.1 Noted

6. Agenda item no. 6 –Minutes of 55thmeeting of Multidisciplinary Committee of Experts held on 17.10.2023.

6.1 Noted

7. Agenda item no. 7 –Approval for ceiling price of different dosage forms and strength of I.V Fluids with packaging in non glass with special features dated 05.06.2023 being filed by M/s Biosynergy Lifecare Pvt. Ltd.

7.1 The Authority noted the application filed by M/s Biosynergy Lifecare Pvt. Ltd for separate price under Para 11(3) of DPCO, 2013 with respect to following formulations as mentioned in **Table 2** in Non-Glass with special features i.e. (i) self collapsibility and self-sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels:

Table No. 2: Details of application filed by M/s Biosynergy Lifecare Pvt. Ltd.

S.No.	Medicines	Dosage form and strength	Unit
1.	Glucose	Injection 5%	500ml & 1000ml Non Glass

S.No.	Medicines	Dosage form and strength	Unit
			with special features
2.	Glucose (A) + Sodium Chloride (B)	Injection 5% (A) + 0.9% (B)	500ml & 1000ml Non Glass with special features
3.	Sodium Chloride	Injection 0.9%	100ml, 500ml & 1000ml Non Glass with special features
4.	Ringer lactate	Injection	500ml & 1000ml Non Glass with special features
5.	Dextrose (Glucose)	Injection 25% w/v	100ml Non Glass with special features
6.	Metronidazole	Injection 0.5%w/v	100ml Non Glass with special features
7.	Mannitol	Injection 20%	100ml Non Glass with special features

7.2 The Authority further noted that the matter was deliberated in various meetings of the Multidisciplinary Committee of Experts (52nd, 53rd & 55th meeting) wherein the product was demonstrated by the applicant and the Committee examined the documents submitted by the company. The Authority also noted that in 55th meeting of the Multidisciplinary Committee of Experts held on 23.10.2023, the Committee recommended " ...to extend ceiling prices for the formulations as mentioned in Table 8.2 above notified vide S.O. No. 1569(E), 1570(E), 1571(E), 1575(E) and 1576(E) dated 31.03.2023 to M/s Biosynergy Lifecare Pvt. Ltd."

7.3 The Authority deliberated upon the matter in detail and accepted the recommendation of Multidisciplinary Committee of Experts to extend the ceiling prices mentioned in S.O. No. 1569(E), 1570(E), 1571(E), 1575(E) and 1576(E) dated 31.03.2023 to M/s Biosynergy Lifecare Pvt. Ltd. for the formulations in Non-Glass with special features under Para 11(3) of DPCO, 2013 as mentioned in **Table 3** below:

Table No. 3: Ceiling prices extended to M/s Biosynergy Lifecare Pvt. Ltd.

S.No	Medicines	Dosage form and strength	Unit	Ceiling price (w.e.f. 01.04.2023 with WPI @12.1218%)	SO No. and date
1.	Glucose	Injection 5%	1000ml Non Glass with special features	95.10	1571(E) dated 31.03.2023
2.	Glucose	Injection 5%	500ml Non Glass with special features	82.27	1571(E) dated 31.03.2023
3.	Glucose (A) + Sodium Chloride (B)	Injection 5% (A) + 0.9% (B)	1000ml Non Glass with special features	99.93	1571(E) dated 31.03.2023
4.	Glucose (A) + Sodium Chloride (B)	Injection 5% (A) + 0.9% (B)	500ml Non Glass with special features	85.51	1571(E) dated 31.03.2023
5.	Sodium Chloride	Injection 0.9%	100ml Non	42.05	1571(E)

S.No	Medicines	Dosage form and strength	Unit	Ceiling price (w.e.f. 01.04.2023 with WPI @12.1218%)	SO No. and date
			Glass with special features		dated 31.03.2023
6.	Sodium Chloride	Injection 0.9%	500ml Non Glass with special features	87.93	1571(E) dated 31.03.2023
7.	Sodium Chloride	Injection 0.9%	1000ml Non Glass with special features	98.49	1571(E) dated 31.03.2023
8.	Ringer lactate	Injection 500 ml	Each 500 ml pack having special features	64.96	1570(E) dated 31.03.2023
9.	Ringer lactate	Injection 1000 ml	Each 1000 ml pack having special features	114.19	1570(E) dated 31.03.2023
10.	Dextrose (Glucose)	Injection (25% w/v) in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features	Per ml	0.24	1569(E) dated 31.03.2023
11.	Metronidazole	Injection (0.5%w/v) /500mg/100ml in 100ml pack for packages in non-glass container in plastic bottle with euro head having special features	Per ml	0.24	1576(E) dated 31.03.2023
12.	Mannitol	Injection 20% in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features	Per ml	0.40	1575(E) dated 31.03.2023

8. Agenda item no. 8 – Application for extension of ceiling price for I.V. Fluid Sodium Chloride 0.9% 100 ml with packing in non-glass with special feature in line with S.O. No. 1500(E) dated 30.03.2022 by M/s Puerto Life Science Pvt. Ltd.

8.1 The Authority noted the application filed by M/s Puerto Life Science Pvt. Ltd. for separate price under Para 11(3) of DPCO, 2013 with respect to Sodium Chloride

injection 0.9% in 100 ml pack in Non-Glass with special features i.e. (i) self collapsibility and self- sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels as notified vide S.O. No. 1500(E) dt. 30.03.2022

8.2 The Authority further noted that the matter was deliberated in 50th, 52nd and 55th meeting of the Multidisciplinary Committee of Experts held on 21.04.2023, 11.07.2023 and 17.10.2023 respectively in which the product was demonstrated by the applicant company and the Committee examined the documents submitted by the applicant company. The committee had also noted that separate ceiling price of said formulation had been notified by NPPA vide SO No. 1500(E) dated 30.03.2022. However, the price of the said formulation has been revised based on WPI vide SO No. 1571 (E) dated 31.03.2023. The Authority noted that Multidisciplinary Committee of Experts in its 55th meeting held on 17.10.2023 recommended "...to extend ceiling prices for the formulations as mentioned in S.O. No. 1571(E) dated 31.03.2023 for Sodium Injection 0.9% in 100ml Non-Glass with special features to M/s Pureto Life Science Pvt. Ltd.". It was noted that the

8.3 The Authority deliberated upon the matter in detail and accepted the recommendation of Multidisciplinary Committee of Experts and decided to extend the ceiling prices mentioned in S.O. No. 1571(E) dated 31.03.2023 for Sodium Injection 0.9% in 100ml Non-Glass with special features to M/s Pureto Life Science Pvt. Ltd. under Para 11(3) of DPCO, 2013 agiven in **Table 4** below:

Table No. 4: Ceiling prices extended to M/s Pureto Life Science Pvt. Ltd.

S.No.	Medicines	Dosage form and strength	Unit	Ceiling price (wef 01.04.2023 with WPI @12.1218%)
1.	Sodium Chloride	Injection 0.9%	100ml Non Glass with special features	Rs. 42.05 per pack (SO No. 1571 dated 31.03.2023)

9. Agenda item no. 9 - Fixation of Ceiling Price of Nine (9) scheduled formulations under Revised Schedule-I (NLEM, 2022)

9.1 The Authority noted that prices of 691 formulations have been notified under NLEM 2022 based on the methodology for fixation of ceiling price of scheduled formulations under revised Schedule-I (NLEM, 2022) that was deliberated in the 104th, 111th and 112th meeting of the Authority held on 23.11.2022, 29.03.2023 and 01.05.2023 respectively.

9.2 The Authority noted that ceiling prices for 10 scheduled formulations were uploaded on the NPPA website on 16.10.2023 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.

9.3 The Authority was apprised that a total of 7 representations for 5 formulations were received from various companies. The companies have submitted copy of invoice(s) showing the revised PTR and/or snapshots of sample pack showing revised MRP. The Authority noted that following types representations have been received:

- 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 dosage form.

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iii. Considering MR variant along with conventional variant in cases where MR variant is separately included in schedule.

The Authority noted that these claims/representations have been cross verified with the Form-II/Form-V submitted by the companies till 15.05.2022 in the IPDMS as per provisions of DPCO, 2013.

9.4 The Authority was informed that in case of Temozolomide Tablets 100 mg all the companies that were considered in draft worksheet have represented that their product are capsules and not tablets as mentioned in the uploaded draft worksheet. Therefore, the same was not placed for deliberations in the meeting.

9.5 The Authority deliberated upon the ceiling price fixation of scheduled formulations and approved the following 7 formulations under Para 4(1) of DPCO 2013 as given in **Table 5** below:

Table 5: Ceiling Price Fixation

S.No.	Section	Formulations	Dosage form (s) and strength (s)	Prevailing Ceiling & Notification No.		New Ceiling Price	Unit
				(5)	(6)		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1.	7.3.4	Tacrolimus	Tablet 1mg	42.83	1573(E) dt. 31.03.23	39.98	1 Tablet
2.	7.3.4	Tacrolimus	Tablet 2mg	84.6	1573(E) dt. 31.03.23	77.69	1 Tablet
3.	7.3.4	Tacrolimus	Tablet 0.5mg	23.32	1573(E) dt. 31.03.23	20.97	1 Tablet
4.	6.2.2.6	Co-trimoxazole [Sulphamethoxazole (A) +Trimethoprim(B)]	Tablet 800 mg (A) + 160 mg (B)	2.52	1573(E) dt. 31.03.23	2.30	1 Tablet
5.	17.6.2	Zinc Sulphate	Dispersible Tablet 20mg	3.91	1573(E) dt. 31.03.23	3.41	1 Tablet
6.	7.4.15	Tramadol	Tablet 50 mg	10.03	1573(E) dt. 31.03.23	9.70	1 Tablet
7.	7.4.15	Tramadol	Tablet 100 mg	24.48	1573(E) dt. 31.03.23	24.48	1 Tablet

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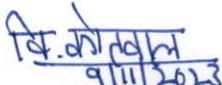
9.5 The Authority deliberated upon the ceiling price fixation of scheduled formulations and approved the following 2 formulations (**Table 6**) under Para 6(1) of DPCO 2013:

Table 6: Ceiling Price fixation in Monopoly cases

S.No.	Section	Formulations	Dosage form(s) and strength (s)	Prevailing Ceiling & Notification No.		New Ceiling Price	Unit
				(5)	(6)		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1.	7.1.34	Temozolomide	Tablet 20mg	466.49	1573(E) dt. 31.03.23	336.63	1 Tablet
2.	7.1.34	Temozolomide	Tablet 250mg	4765.73	1573(E) dt. 31.03.23	3757.94	1 Tablet

Note: The ceiling prices of above 2 formulations were uploaded without applying monopoly reductions under Para 6. However, based on the representation received w.r.t. incorrect dosage form only one company qualified with more than 1 per cent market share. Hence, ceiling price fixed by applying monopoly reduction as per under Para 6(1) of DPCO, 2013 applied.

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


 9/11/2023
(Dr. Vinod Kotwal)
 Member Secretary