

मिसिलस.- 8(132)/2025/डी.पी/एनपीपीए-डीवी-II

F. No. 8(132)/2025/DP/NPPA-Div. II

कार्यवाहीस. : 264/132/2025/F

Proceeding No: 264/132/2025/F

Minutes of the 264th (overall) and 132nd meeting of the Authority under DPCO, 2013 held on 29.04.2025 at 03:00 P.M.

The 264th meeting of the Authority (overall), which is the 132nd meeting under the DPCO, 2013 was held on 29th April, 2025 at 03:00 P.M. under the Chairmanship of Shri P. Krishnamurthy, Chairman, NPPA. The following Authority members were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri Manmohan Sachdeva, Additional Chief Adviser Cost (ACAC), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) Dr. Rose Mary K. Abraham, Economic Advisor, Department of Economic Affairs

Shri Ranga Chandrashekar, Joint Drug Controller, CDSCO, Ministry of Health & Family Welfare.

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

- (i) Shri Sanjay Kumar, Advisor (Cost)
- (ii) Ms. Rashmi Tahiliani, Director (Pricing)
- (iii) Shri Mahaveer Saini, Deputy Director (Pricing)

1. Agenda item no. 1 - Confirmation of Minutes of the 131st Meeting held on 25.03.2025.

1.1 The Authority confirmed the minutes of the meeting without any change.

2. Agenda item no. 2 - Action Taken Report (ATR) on decisions taken by NPPA in its 131st Meeting held on 25.03.2025.

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 deliberated on 85 (Eighty-five) cases of retail price fixation of new drugs as presented in Agenda no. 4 (1) to 4 (83) falling under the purview of Para 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of 84 (Eighty-four) new drugs under Para 5 and 15 of the DPCO 2013 as given in **Table 1** below-

Table No. 1: Retail price fixation of new drugs

S. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	4(1)	Aspirin (gastro-resistant) & Atorvastatin Capsules	Each hard gelatin capsule contains: Aspirin IP 75 mg (as gastro-resistant tablet IP) Atorvastatin Calcium IP eq. to Atorvastatin 40 mg	1 Capsule	M/s Windlas Biotech Ltd. M/s Mankind Pharma Ltd.	18.27
2	4(2)	Atorvastatin & Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP equivalent to Atorvastatin 10mg Ezetimibe IP 10mg	1 Tablet	M/s Safetab Life Science/ M/s Ajanta Pharma Ltd.	Deferred (Note 1)
3	4(3)	Atorvastatin & Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP equivalent to Atorvastatin 40mg Ezetimibe IP 10mg	1 Tablet	M/s Safetab Life Science/ M/s Ajanta Pharma Ltd.	30.47
4	4(4)	Atorvastatin & Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP equivalent to Atorvastatin 80mg Ezetimibe IP 10mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Ipca Laboratories Ltd.	54.29
5	4(5)	Bisoprolol Fumarate & Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5 mg Telmisartan IP 40 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s BDR Pharmaceuticals International Pvt. Ltd.	9.10
6	4(6)	Bisoprolol Fumarate & Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5 mg Telmisartan IP 40 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s BDR Pharmaceuticals	12.19

S. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
					International Pvt. Ltd.	
7	4(7)	Budesonide & Formoterol Fumarate Respirator Suspension	Each 2 ml contains: Budesonide IP 1 mg Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 20 mcg	Per 2ml respule	M/s Axa Parenterals Ltd./ M/s Mankind Pharma Ltd.	64.25
8	4(8)	Cefixime Oral Suspension	Each 5 ml of reconstituted suspension contains: Cefixime IP Equivalent to Cefixime Anhydrous 200 mg	1 ml	M/s Alps Communication Pvt. Ltd./ M/s Mankind Pharma Ltd.	3.72
9	4(9)	Ceftriaxone, Disodium Edetate & Sulbactam Sodium powder for solution for infusion	Each vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 1000 mg, Disodium Edetate IP 37 mg Sulbactam Sodium IP eq. to Sulbactam 500 mg	1 Vial	M/s BDR Pharmaceuticals International Pvt Ltd./ M/s Zydus Healthcare Ltd.	515.57
10	4(10)	Ceftriaxone, Disodium Edetate & Sulbactam Sodium powder for solution for infusion	Each vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 2000 mg, Disodium Edetate IP 74 mg Sulbactam Sodium IP eq. to Sulbactam 1000 mg	1 Vial	M/s BDR Pharmaceuticals International Pvt Ltd./ M/s Zydus Healthcare Ltd.	1036.60
11	4(11)	Clonazepam & Paroxetine (CR) tablets	Each film coated bilayered tablet contains: Clonazepam IP 0.5 mg Paroxetine Hydrochloride Hemihydrate IP eq. to Paroxetine 12.5 mg (as Controlled Release)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Torrent Pharmaceuticals Ltd.	16.02
12	4(12)	Clonazepam & Paroxetine (CR) tablets	Each film coated bilayered tablet contains: Clonazepam IP 0.5 mg Paroxetine Hydrochloride Hemihydrate IP eq. to Paroxetine 25 mg (as Controlled Release)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Torrent Pharmaceuticals Ltd.	18.70
13	4(13)	Combipack of Ceftriaxone &	Twin Pack Contains: (a) One vial of Ceftriaxone	1 Vial	M/s Prosperity 6 Pharmaceuticals/	194.68

S. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Tazobactam for Injection	& Tazobactam for Injection IP: Sterile Ceftriaxone Sodium IP Eq. to Ceftriaxone 1000 mg Sterile Tazobactam Sodium IP Eq. to Tazobactam 125 mg (b) Each ampoule contains: 10 ml Sterile Water for Injections IP		M/s Lupin Life Sciences Ltd.	
14	4(14)	Esomeprazole Magnesium & Domperidone (SR) Capsules	Each hard gelatin capsule contains: Esomeprazole Magnesium Trihydrate IP equivalent to Esomeprazole 40 mg (as enteric coated pellets) Domperidone IP 30 mg (as sustained release pellets)	1 Capsule	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Troikaa Pharmaceuticals Ltd.	12.35
15	4(15)	Glimepiride, Voglibose & Metformin Hydrochloride (SR) Tablets	Each uncoated bilayered tablet contains: Glimepiride IP 0.5 mg Voglibose IP 0.2 mg Metformin Hydrochloride IP 500 mg (Sustained release form)	1 Tablet	M/s Windlas Biotech Ltd./ M/s USV Ltd.	9.12
16	4(16)	Lactitol Monohydrate & Ispaghula Husk Granules	Each 15 g granules contains: Lactitol Monohydrate USP - NF 10 g Ispaghula Husk IP 3.5 g	1 gm	M/s Tirupati Medicare Ltd./ M/s Emcure Pharmaceuticals Ltd.	2.51
17	4(17)	Mefenamic Acid & Paracetamol Suspension	Each 5 ml contains: Mefenamic Acid IP 100 mg Paracetamol IP 250 mg	1 ml	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	0.90
18	4(18)	Mycophenolate Mofetil Tablets	Each film coated tablet contains: Mycophenolate Mofetil IP 750 mg	1 Tablet	M/s Rivpra Formulations Pvt. Ltd./ M/s RPG Life Sciences Ltd.	112.00
19	4(19)	Paracetamol & Caffeine Tablets	Each uncoated tablet contains: Paracetamol IP 650 mg Caffeine (Anhydrous) IP 50 mg	1 Tablet	M/s Prochem Pharmaceuticals Pvt. Ltd./ M/s Mankind	3.63

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(1)	(2)	(3)	(4)	(5)	(6)	(7)
					Consumer Products Pvt. Ltd.	
20	4(20)	Paracetamol & Ibuprofen Suspension	Each 5 ml contains: Paracetamol IP 162.5 mg Ibuprofen IP 100 mg	1 ml	M/s Parrish Pharmaceuticals Pvt. Ltd./ M/s Alembic Pharmaceuticals Ltd.	0.53
21	4(21)	Paracetamol & Mefenamic Acid Suspension	Each 5 ml contains: Paracetamol IP 250 mg Mefenamic Acid IP100 mg	1 ml	M/s Parrish Pharmaceuticals Pvt. Ltd./ M/s Alembic Pharmaceuticals Ltd.	0.90
22	4(22)	Paracetamol Infusion	Each 100 ml contains: Paracetamol IP 1000 mg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Workcell Solutions Pvt. Ltd.	3.39
23	4(23)	Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Tablet	Each uncoated tablet contains: Paracetamol IP 500 mg Phenylephrine Hydrochloride IP 10 mg Chlorpheniramine Maleate IP 2 mg	1 Tablet	M/s East African (India) Overseas/ M/s Glensmith Labs Pvt. Ltd.	4.96
24	4(24)	Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Tablet	Each uncoated tablet contains: Paracetamol IP 500 mg Phenylephrine Hydrochloride IP 10 mg Chlorpheniramine Maleate IP 2 mg	1 Tablet	M/s East African (India) Overseas/ M/s Jagsonpal Pharmaceuticals Ltd.	4.96
25	4(25)	Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Tablet	Each uncoated tablet contains: Paracetamol IP 500 mg Phenylephrine Hydrochloride IP 10 mg Chlorpheniramine Maleate IP 2 mg	1 Tablet	M/s East African (India) Overseas / M/s Mankind Prime Labs Pvt. Ltd.	4.96
26	4(26)	Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Tablet	Each uncoated tablet contains: Paracetamol IP 500 mg Phenylephrine Hydrochloride IP 10 mg Chlorpheniramine Maleate IP 2 mg	1 Tablet	M/s East African (India) Overseas/ M/s Glenmark Pharmaceuticals Ltd.	5.13

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(1)	(2)	(3)	(4)	(5)	(6)	(7)
27	4(27)	Cilnidipine & Telmisartan Tablets	Each film coated tablet contains: Cilnidipine IP 20 mg Telmisartan IP 40 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Micro Labs Ltd.	11.07
28	4(28)	Cilnidipine, Telmisartan & Metoprolol Succinate (Extended Release) Tablets	Each film coated tablet contains: Cilnidipine IP 10 mg Telmisartan IP 40 mg Metoprolol Succinate 23.75 mg Eq. to Metoprolol Tartrate 25 Mg (Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Cadila Pharmaceuticals Ltd.	11.02
29	4(29)	Cilnidipine, Telmisartan & Metoprolol Succinate (Extended Release) Tablets	Each film coated tablet contains: Cilnidipine IP 10 mg Telmisartan IP 40 mg Metoprolol Succinate 47.5 mg Eq. to Metoprolol Tartrate 50 Mg (Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Cadila Pharmaceuticals Ltd.	13.78
30	4(30)	Telmisartan & Metoprolol Succinate (ER) tablets	Each film coated tablet contains: Telmisartan IP 40 mg Metoprolol Succinate IP 50 mg (as extended release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	16.29
31	4(31)	Telmisartan, Cilnidipine & Chlorthalidone Tablets	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Micro labs Ltd.	14.51
32	4(32)	Telmisartan, Cilnidipine & Chlorthalidone Tablets	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd./ M/s Intas Pharmaceuticals Ltd.	15.21
33	4(33)	Telmisartan, Metoprolol Succinate (ER) & Chlorthalidone Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40 mg, Metoprolol Succinate IP 23.75 mg eq. to Metoprolol Tartrate 25 mg (as Extended Release), Chlorthalidone IP 12.5 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Alembic Pharmaceuticals Ltd.	11.30

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(1)	(2)	(3)	(4)	(5)	(6)	(7)
34	4(34)	Telmisartan, Metoprolol Succinate (ER) & Chlorthalidone Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40 mg, Metoprolol Succinate IP 23.75 mg eq. to Metoprolol Tartrate 25 mg (as Extended Release), Chlorthalidone IP 6.25 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Alembic Pharmaceuticals Ltd.	10.52
35	4(35)	Telmisartan, Metoprolol Succinate (ER) & Chlorthalidone Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40 mg, Metoprolol Succinate IP 47.5 mg eq. to Metoprolol Tartrate 50 mg (as Extended Release), Chlorthalidone IP 12.5 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Alembic Pharmaceuticals Ltd.	13.70
36	4(36)	Telmisartan, Metoprolol Succinate (ER) & Chlorthalidone Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40 mg, Metoprolol Succinate IP 47.5 mg eq. to Metoprolol Tartrate 50 mg (as Extended Release), Chlorthalidone IP 6.25 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Alembic Pharmaceuticals Ltd.	10.73
37	4(37)	Dapagliflozin, Glimepiride & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10 mg Glimepiride IP 1 mg Metformin Hydrochloride IP 1000 mg (as extended release form)	1 Tablet	M/s Windlas Biotech Ltd. / M/s USV Ltd.	12.08
38	4(38)	Dapagliflozin, Glimepiride & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 1000 mg (as extended release form)	1 Tablet	M/s Windlas Biotech Ltd. / M/s USV Ltd.	12.90
39	4(39)	Empagliflozin & Metformin	Each film coated tablet contains:	1 Tablet	M/s Innova Captab Ltd./	19.64

S. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Hydrochloride Tablets	Empagliflozin 12.5mg Metformin Hydrochloride IP 1000mg		M/s Corona Remedies Ltd.	
40	4(40)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	19.64
41	4(41)	Empagliflozin & Metformin Hydrochloride (ER) tablets	Each Film coated bilayered tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg (As Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Mankind Pharma Ltd.	19.64
42	4(42)	Empagliflozin & Metformin Hydrochloride Tablets	Each Film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Macleods Pharmaceuticals Limited	19.64
43	4(43)	Empagliflozin & Metformin Hydrochloride Tablets	Each Film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Windlas Biotech Ltd. M/s Zuventus Healthcare Ltd.	19.64
44	4(44)	Empagliflozin & Metformin Hydrochloride Tablets	Each Film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	19.64
45	4(45)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Innova Captab Ltd./ M/s Corona Remedies Ltd.	18.10
46	4(46)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	18.10
47	4(47)	Empagliflozin & Metformin Hydrochloride Tablets	Each Film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Macleods Pharmaceuticals Limited	18.10

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(1)	(2)	(3)	(4)	(5)	(6)	(7)
48	4(48)	Empagliflozin & Metformin Hydrochloride Tablets	Each Film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Windlas Biotech Ltd. M/s Zuventus Healthcare Ltd.	18.10
49	4(49)	Empagliflozin & Metformin Hydrochloride Tablets	Each Film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. M/s German Remedies Pharmaceuticals Pvt. Ltd.	18.10
50	4(50)	Empagliflozin & Metformin Hydrochloride Tablets	Each Film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. M/s Alkem Laboratories Ltd.	18.10
51	4(51)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	15.84
52	4(52)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s Jagsonpal Pharmaceuticals Ltd.	15.84
53	4(53)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	15.84
54	4(54)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Alkem Laboratories Ltd.	15.84
55	4(55)	Empagliflozin & Metformin Hydrochloride (ER) tablets	Each Film coated bilayered tablet contains: Empagliflozin 10 mg Metformin Hydrochloride IP 1000 mg (as Extended release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Lupin Ltd.	17.86

S. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
56	4(56)	Empagliflozin & Metformin Hydrochloride (ER) tablets	Each Film coated bilayered tablet contains: Empagliflozin 10 mg Metformin Hydrochloride IP 1000 mg (as Extended release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Mankind Pharma Ltd.	22.96
57	4(57)	Empagliflozin & Metformin Hydrochloride (ER) tablets	Each film coated bilayered tablet contains: Empagliflozin 25 mg Metformin Hydrochloride IP 1000 mg (As Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Lupin Ltd.	22.32
58	4(58)	Empagliflozin & Metformin Hydrochloride (ER) tablets	Each film coated bilayered tablet contains: Empagliflozin 25 mg Metformin Hydrochloride IP 1000 mg (As Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Micro Labs Ltd.	26.31
59	4(59)	Empagliflozin & Metformin Hydrochloride (ER) Tablets	Each Film coated bilayered tablet contains: Empagliflozin 25 mg Metformin Hydrochloride IP 1000 mg (As Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Mankind Pharma Ltd.	25.00
60	4(60)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	11.10
61	4(61)	Empagliflozin & Metformin Hydrochloride (ER) tablets	Each Film coated bilayered tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 1000 mg (as Extended release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Mankind Pharma Ltd.	11.55
62	4(62)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. M/s German Remedies Pharmaceuticals Pvt. Ltd.	11.10

S. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
63	4(63)	Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg Metformin Hydrochloride IP 500 mg (As Extended Release)	1 Tablet	M/s Synokem Pharmaceuticals Limited/ M/s Mankind Pharma Ltd.	12.91
64	4(64)	Sitagliptin, Glimepiride & Metformin Hydrochloride tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 1 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s USV Ltd.	11.16
65	4(65)	Sitagliptin, Glimepiride & Metformin Hydrochloride tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s USV Ltd.	12.59
66	4(66)	Paracetamol Infusion	Each 100 ml contains: Paracetamol IP 1000mg	1 ml	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Hetero Healthcare Ltd.	2.47 (Note 2)
67	4(66)	Paracetamol Infusion	Each 100 ml contains: Paracetamol IP 1000mg	1 ml	M/s Abaris Healthcare Pvt. Ltd. / M/s Hetero Healthcare Ltd.	2.47 (Note 2)
68	4(67)	L-Carnitine, Methylcobalamin & Folic Acid Tablets	Each film coated tablet contains: L-Carnitine L-Tartrate eq. to L-Carnitine 500mg, Methylcobalamin IP 1500mcg & Folic Acid IP 1.5mg	1 Tablet	M/s Merrill Pharma Pvt. Ltd. / M/s Ozone Pharmaceuticals Limited	6.11 (Note 2)
69	4(68)	Rosuvastatin, Aspirin & Clopidogrel Tablets	Each Capsule contains: Rosuvastatin Calcium IP equivalent to Rosuvastatin 10mg + Aspirin IP 75mg (As enteric coated) + Clopidogrel Bisulphate IP equivalent to Clopidogrel 75mg	1 Capsule	M/s. Pure and Cure Healthcare Pvt. Ltd / M/s. Unimed Technologies Ltd.	10.37 (Note 2)

S. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
70	4(68)	Rosuvastatin, Aspirin & Clopidogrel Tablets	Each Capsule contains: Rosuvastatin Calcium IP equivalent to Rosuvastatin 20mg + Aspirin IP 75mg (as enteric coated) + Clopidogrel Bisulphate IP equivalent to Clopidogrel 75mg	1 Capsule	M/s. Pure and Cure Healthcare Pvt. Ltd / M/s. Unimed Technologies Ltd.	18.56 (Note 2)
71	4(69)	Clotrimazole Vaginal Film	Each vaginal film contains: Clotrimazole IP 50 mg	1 Vaginal Film	M/s Hetero Healthcare Ltd.	6.01
72	4(70)	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) tablets	Each film coated tablet contains: Empagliflozin 10 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Lupin Ltd.	22.32
73	4(71)	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) tablets	Each film coated tablet contains: Empagliflozin 10 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Mankind pharma Ltd.	29.08
74	4(72)	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) tablets	Each film coated tablet contains: Empagliflozin 10 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Eris Lifesciences Ltd.	29.08
75	4(73)	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) tablets	Each film coated tablet contains: Empagliflozin 10 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Cipla Ltd.	25.00
76	4(74)	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) tablets	Each film coated tablet contains: Empagliflozin 25 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Lupin Ltd.	23.21
77	4(75)	Empagliflozin, Linagliptin &	Each film coated tablet contains:	1 Tablet	M/s Pure and Cure Healthcare Pvt.	32.43

S. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Metformin Hydrochloride (ER) tablets	Empagliflozin 25 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)		Ltd./ M/s Mankind pharma Ltd.	
78	4(76)	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) tablets	Each film coated tablet contains: Empagliflozin 25 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Micro Labs Ltd.	33.23
79	4(77)	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) tablets	Each film coated tablet contains: Empagliflozin 25 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Eris Lifesciences Ltd.	33.23
80	4(78)	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) tablets	Each film coated tablet contains: Empagliflozin 25 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Intas Pharmaceuticals Ltd.	15.00
81	4(79)	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) tablets	Each film coated tablet contains: Empagliflozin 25 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Cipla Ltd.	29.00
82	4(80)	Empagliflozin & Metformin Hydrochloride (SR) Tablets	Each film coated tablet contains: Empagliflozin 25 mg Metformin Hydrochloride IP 1000 mg (as Sustained release)	1 Tablet	M/s Abbott Healthcare Pvt. Ltd.	21.43
83	4(81)	Empagliflozin & Metformin Hydrochloride (SR) Tablets	Each film coated tablet contains: Empagliflozin 10 mg Metformin Hydrochloride IP 1000 mg (as Sustained release)	1 Tablet	M/s Abbott Healthcare Pvt. Ltd.	16.96
84	4(82)	Cholecalciferol (Vitamin D3) Oral Solution	Each 5ml contains: Cholecalciferol IP (in Nano Droplet Form) 60000 IU	1 ml	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s German	14.94 (Note 3)

S. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
					Remedies Pharmaceuticals Pvt. Ltd.	
85	4(83)	Cholecalciferol (Vitamin D3) Oral Solution	Each 5ml contains: Cholecalciferol IP 60000 IU	1 ml	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Cipla Ltd.	15.03 (Note 4)

Note 1: The Authority directed to reexamine the data of the subject formulation and accordingly, the agenda was deferred.

Note 2: The Authority noted that agenda item no. 4(66) to 4(68) as mentioned at Sr. No. 66 to 70 in the table above are cases of launch without price approval. Accordingly, the Authority approved the lowest of the launched price, worked out price and claimed price (if any).

Note 3: The Authority noted that worksheet with proposed price of Rs. 17.32 per ML was uploaded on NPPA website on 07.02.2025. However, the Authority in its 130th meeting held on 25.02.2025 directed to re-examine the data in the worksheet. Accordingly, the revised draft worksheet with proposed price of Rs. 15.15 per ML based on clarification from Pharmarack was uploaded on 06.03.2025. However, based on representation from M/s German Remedies Pharmaceuticals Pvt. Ltd, the price has been further revised to Rs. 14.94 per ML (draft worksheet uploaded on 09.04.2025) based on re-confirmation of data from Pharmarack.

Note 4: The Authority noted that the draft worksheet was uploaded on 06.03.2025 with proposed price at Rs. 14.96 per ML. However, the uploaded price was revised to Rs. 15.03 per ML on 09.04.2025 in view of the revision in the Pharmarack data as represented by M/s German Remedies Pharmaceuticals Pvt. Ltd.

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

5.1 Noted.

6. Agenda item no. 6: Minutes of 67th meeting of Multidisciplinary Committee of Experts held on 02.04.2025

6.1 Noted.

7. Agenda item no. 7: Request for consideration of Price Fixation under Para 11(3) of DPCO-2013 for "Each 100ml contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 900mg- in 500ml pack" with pack of non-glass container in plastic bottle with Euro head having special features filed by M/s Otsuka Pharmaceutical India Pvt. Ltd (F. No 19(3936))

7.1 The Authority noted that M/s Otsuka Pharmaceuticals India Pvt. Ltd. filed application on 27.03.2024 for retail price fixation of the formulation 'Each 100ml contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 900mg- in 500ml pack". The Authority recalled that MDC recommended a price of Rs. 45.51 per 500 ml pack in its 61st meeting by treating the application as normal retail price application since the applicant had not mentioned that application is under para 11 (3) of DPCO, 2013. However, based on the representation of the applicant dated 27.08.2024 as placed in the 126th Authority meeting held on 09.09.2024; the Authority directed that applicant may be asked to resubmit the application under Para 11(3). Accordingly, the applicant vide letter dated 12.09.2024 submitted for consideration of the application under para 11(3).

7.2 The Authority noted that the matter has been accordingly deliberated in 62nd to 64th MDC, wherein the MDC examined the application for the special features claimed by the applicant. After detailed deliberations and demonstration made by the company, the MDC in its 64th meeting held on 06.12.2024 recommended a price of the captioned formulation at Rs. 92.82 per 500 ml pack. It was noted that the company vide letter dated 21.01.2025 and 07.03.2025 represented on the other two formulations as mentioned below:

- i. Each 100ml contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 450 mg- in 500ml pack", and
- ii. Multiple electrolytes and 5% Dextrose injection Type I USP for pack of non-glass container in plastic bottle with Euro Head and Non-PVC bag having special feature under Para 11(3) of DPCO detailing the key issues in the pricing of the said formulations.

Since all the three applications were examined holistically by the MDC earlier, the matter was placed again in the 67th MDC meeting held on 02.04.2025 after examination of the representations.

7.3 The Authority noted that the MDC reiterated its earlier recommended price at Rs. 92.82 per 500 ml pack for the said formulation. The Authority deliberated upon the matter and approved the price for "Each 100ml contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 900mg- in 500ml pack" as recommended by the MDC at Rs. 92.82 per 500 ml pack with pack of non-glass container in plastic bottle with Euro head having special features for M/s Otsuka Pharmaceuticals India Pvt. Ltd.

8. Agenda item no. 8: Request for consideration of Price Fixation under Para 11(3) of DPCO-2013 for "Each 100ml contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 450mg- in 500ml pack" with pack of non-glass container in plastic bottle with Euro head having special features filed by M/s Otsuka Pharmaceutical India Pvt. Ltd. (F. No. 19(3947))

8.1 The Authority noted that M/s Otsuka Pharmaceuticals India Pvt Ltd. filed application on 27.03.2024 for retail price fixation of the formulation 'Each 100ml

contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 450mg- in 500ml pack". The Authority recalled that MDC recommended a price of Rs. 33.81 per 500 ml pack in its 61st meeting by treating the application as normal retail price application since the applicant did not mention that application is under para 11(3) of DPCO, 2013. However, based on the representation of the applicant dated 27.08.2024 as placed in the 126th Authority meeting held on 09.09.2024, the Authority directed that application may be asked to resubmit the application under Para 11(3). Accordingly, the applicant vide letter dated 12.09.2024 submitted for consideration of the application under para 11(3).

8.2 The Authority noted that the matter has been accordingly deliberated in 62nd to 64th MDC, wherein the MDC examined the application for the special features claimed by the applicant. After detailed deliberations and demonstration made by the company, the MDC in its 64th meeting held on 06.12.2024 recommended a price of the captioned formulation at Rs. 68.30 per 500 ml pack. It was noted that the company vide letter dated 21.01.2025 and 07.03.2025 represented that the price of Dextrose Monohydrate IP 5000mg or Glucose Injection 5% has been considered at Rs. 2.52 for a pack of 100 ml, whereas the applied pack size is of 500 ml.

8.3 Accordingly, the matter was deliberated in 67th meeting of MDC held on 02.04.2025. The Committee re-examined the matter and observed that the required API quantity of Dextrose in 500ml pack is 25 grams whereas while working out the recommended price, price of 5 grams of API was considered. Accordingly, the Committee re-worked the price and recommended the price of Rs. 75.67 per 500ml pack.

8.4 The Authority deliberated upon the matter and approved the recommended price at Rs. 75.67 per 500 ml pack "Each 100ml contains: Potassium Chloride IP 150mg + Dextrose Monohydrate IP 5000mg + Sodium Chloride IP 450mg- in 500ml pack" with pack of non-glass container in plastic bottle with Euro head having special features for M/s Otsuka Pharmaceuticals India Pvt. Ltd.

9. Agenda item no. 9: Request for consideration of Price fixation for Multiple electrolytes and 5% Dextrose injection Type I USP for pack of non-glass container in plastic bottle with Euro Head and Non-PVC bag having special feature under Para 11(3) of DPCO, 2013 as applied by M/s Otsuka Pharmaceuticals India Pvt. Ltd. (Manufacturer & Marketer). (F. No. 19(4182))

9.1 The Authority noted that M/s Otsuka Pharmaceuticals India Pvt Ltd. filed application on 01.08.2024 for retail price fixation for the formulation each 100 ml contains: Sodium Chloride IP 526 mg + Sodium Gluconate USP 502 mg + Sodium Acetate Trihydrate IP 368 mg + Potassium Chloride IP 37 mg + Magnesium Chloride Hexahydrate IP 30 mg + Dextrose Monohydrate IP 5000 mg- for 500ml pack of non-glass container in plastic bottle with Euro Head and Non-PVC bag having special feature. The Authority noted that the matter was deliberated in 63rd and 64th meeting of MDC, wherein the applicant demonstrated the product and MDC examined the application for the special features claimed by the applicant. After detailed deliberations the Committee in its 64th meeting held on 06.12.2024 recommended separate retail price of Rs. 81.56 per 500ml.

9.2 The Authority further noted that the applicant company represented vide letter dated 21.01.2025 and 07.03.2025 requesting to review the retail price of the subject formulation on the basis of price of multiple electrolytes (being the product of same composition) and the price of dextrose 5% available in the market. The applicant also requested to review the price on the basis of literature provided by them.

9.3 Accordingly, the matter was deliberated in 67th meeting of MDC held on 02.04.2025. The Committee noted that data for the "Multiple electrolytes" is available in the IPDMS. Accordingly, the Committee deliberated that since the exact composition of subject formulation excluding 5% Dextrose injection is available, the retail price of the subject formulation may be calculated based on price of Multiple Electrolyte in plastic bottle plus 15% for innovation on account of special packaging as per the current practice and price of 5% Dextrose injection may be added to the same. Accordingly, the Committee recommended the revised retail price for the subject formulation **for pack of non-glass container in plastic bottle with Euro Head and Non-PVC bag** having special feature at Rs. 151.89 per 500ml pack.

9.4 The Authority deliberated upon the matter in detail and approved the price recommended by MDC for the subject formulation for pack of non-glass container in plastic bottle with Euro Head and Non-PVC bag having special feature at Rs. 151.89 per 500ml pack for M/s Otsuka Pharmaceuticals India Pvt. Ltd.

10. Agenda item No. 10: Fixation of Ceiling prices of 9 scheduled formulations under Revised Schedule-I (NLEM, 2022)

10.1 The Authority noted that ceiling price of 755 formulations have been fixed 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 and 111th meeting of the Authority held on 23.11.2022 and 29.03.2023 respectively. Further, the Authority also recalled the decision taken in 120th meeting held on 24.01.2024, wherein it was decided to use October 2023 database and the month of October, 2023 for fixation of the ceiling prices of remaining formulations under NLEM, 2022 under para 9 (7) of DPCO, 2013. Further, the Authority in its 130th meeting held on 25.02.2025 decided that in the remaining cases of ceiling price fixation, in case the qualifying items as per Pharmarack database are less than five (5), data from other sources i.e. IPDMS Form II/V, web sources, market survey or any other source may be explored for identification of other manufacturers in line with Para 9(1) of DPCO, 2013.

10.2 The Authority noted that based on approved methodology, draft working sheets for ceiling prices for 9 formulations were uploaded on NPPA website on 09.04.2025 for 10 working days based on database of October 2023 & month of October 2023. Further, the effect of WPI for 2025 i.e. (+) 1.74028% (effective from 01.04.2025) has also been given in the uploaded draft worksheet. As per directions of Authority in its 130th meeting efforts were made for identifying other companies through IPDMS / Web sources. Since, no other companies have been identified, the ceiling prices are proposed based on data as appearing in Pharmarack.

10.3 The Authority noted that no representations have been received for 6 formulations. The representation received in respect of Surfactant Suspension for intra tracheal instillation from M/s Paviour Pharmaceuticals Pvt. Ltd. for consideration of MAT



value on the basis of data provided by the company was examined and it was observed that since the data is available in Pharmarack database, same has been considered for ceiling price fixation as per practice. Further, even if the MAT value as mentioned in the representation of the company is considered, it will not impact the uploaded ceiling price.

10.4 The Authority also noted that with respect to the formulation- 5 - Amino salicylic acid (Mesalazine/ Mesalamine): Retention Enema (Foam and liquid), M/s Sun Pharma had represented for change in pack size, PTR of Enema in liquid form. The same was verified from Form II submitted by the company and accordingly corrected. However, the representation that ceiling price should not be fixed for retention enema as its strength is not specified in NLEM was not agreed by the Authority as ceiling prices of various such formulations have already been fixed under NLEM 2022.

10.5 The Authority also observed that consequent to the changes in the uploaded price of Retention Enema (liquid), the uploaded ceiling price for 5 - amino salicylic acid (Mesalazine/ Mesalamine): Suppository and Retention enema (foam) need to be revised due to applicability of monopoly restriction.

10.6 The authority deliberated upon the uploaded proposed ceiling prices and approved the ceiling prices for 9 formulations as mentioned in **Table 2** below-

Table No. 2: Revised ceiling prices of 9 formulations under NLEM, 2022

S. No.	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Price (in Rs.)	Ceiling Price under NLEM, 2022 (in Rs.)	Unit
1.	5 - amino salicylic acid (Mesalazine/ Mesalamine)	Suppository 500mg	21.42	17.74	1 Suppository
2.	5 - amino salicylic acid (Mesalazine/ Mesalamine)	Retention Enema (Foam)	Not fixed	17.00	1 GM
3.	5 - amino salicylic acid (Mesalazine/ Mesalamine)	Retention Enema (Liquid)	Not fixed	2.16	1 ML
4.	Surfactant	Suspension for intra tracheal instillation (As licensed)	84.72	80.37	1 MG of Phospholipids in the pack
5.	Betamethasone valerate	Lotion 0.05%	0.67	0.67	1 ML
6.	Betamethasone valerate	Gel 0.05%	0.67	0.48	1 GM
7.	Efavirenz	Capsule 600 mg	79.45	56.66	1 Capsule
8.	Rifampicin	Tablet 300mg	3.72	3.70	1 Tablet
9.	Ibuprofen	Capsule 400mg	1.33	1.33	1 Capsule

Agenda item No. 11 Revision of ceiling price based on Review Orders under NLEM, 2022

11.1 The Authority noted that DoP has issued review order No. 31015/54/2023-Pricing and 31015/55/2023-Pricing dated 27.12.2024 in respect of the scheduled formulation Iohexol injection 300 mg iodine/ml stating that the claim of the applicant companies cannot be denied and that as a special case of drug being mainly sold to diagnostic centers and hospitals, NPPA may utilize the powers given to it under paras 9(1) and 9(7) of DPCO, 2013 to explore the other database to capture the representative market for ceiling price fixation in the present case.

11.2 The Authority noted that in compliance to the review orders, letters were sent to the seven manufacturing/marketing companies mentioned in the review order requesting for data for Iohexol injection containing Iodine 300ml for July, 2022.

11.3 Based on the data received from the companies, the revised draft working sheet was uploaded on NPPA website on 09.04.2025. The details of prevailing ceiling price and revised ceiling price are shown in **Table 3** below-

Table No. 3: Ceiling Price of Iohexol 300mg iodine/ml

Particulars	Ceiling Price notified (in Rs.) per ml	Proposed Ceiling Price Revised based review order (in Rs.) per ml
Fixed in March 2023	15.07	17.30
Add: WPI @12.1218%	1.82	2.10
w.e.f. 01.04.2023	16.90	19.40
Add: WPI @0.00551%	0.00	0.00
w.e.f. 01.04.2024	16.90	19.40
Add: WPI @ 1.74028%	0.29	0.34
w.e.f. 01.04.2025	17.19	19.74

11.4 The Authority noted that no representation has been received for the draft worksheet uploaded. Accordingly, the Authority approved the ceiling price of Iohexol injection 300 mg iodine /ml at Rs.19.74 inclusive of WPI revision of April 2025.

Agenda item no. 12: Revision in retail price fixed under Para 5 of DPCO, 2013 under Suo-moto Correction Framework for Each 5 ml Contains: Cholecalciferol IP (In Nano Droplet form) 60000 IU- reg.

12.1 The Authority recalled that NPPA has notified the retail prices of **Cholecalciferol IP 60000 IU Drops** for M/s Aristo Laboratories Pvt. Ltd. (Marketer) & M/s Ravenbhel Healthcare Pvt. Ltd. (Manufacturer) at Rs. 18.93 per ml and M/s Macleods Pharmaceuticals Ltd. (Marketer) & M/s Ravenbhel Healthcare Pvt. Ltd. (Manufacturer) at Rs. 20.23 per ml vide S.O. 5493(E) dated 19.12.2024.

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12.2 The Authority noted that subsequently NPPA received Form I application from M/s German Remedies Pharmaceuticals Private Limited on 16.12.2024 for the same formulation. The matter was placed in 130th meeting of the Authority held on 25.02.2025 with proposed retail price of Rs. 17.92 per ml wherein the Authority deliberated on the matter and directed to reexamine the data as considered in the worksheet. Accordingly, based on clarification received from Pharmarack on data, revised draft working sheet was uploaded on website on 06.03.2025 with proposed price of Rs. 15.15 per ml. However, M/s German Remedies Pharmaceuticals Private Limited vide email dated 11.03.2025 filed representation against the revised draft working sheet uploaded on 06.03.2025. It was noted that representation was made with respect to the different number of line items considered at different points of time while fixing the prices in the past and with respect to PTR of certain line items as considered while fixing the price for M/s German Remedies viz a viz other companies. Accordingly, clarification was sought on data from Pharmarack again. Based on the data as confirmed by Pharmarack and the changes in data being made retrospectively, it was observed that prices fixed earlier in respect of M/s Aristo and M/s Macleods would need price revision.

12.3 The Authority noted the Pharmarack has revised the PTR of some SKUs clarifying that *"PTR corrections were due to stockists maintaining the stock in BOX packs, without box pack description. Now they have accordingly corrected the data."* In the light of the frequent changes made by Pharmarack, the matter related to retail price fixation of subject formulation as referred by M/s German Remedies Pharmaceuticals Pvt. Ltd in their representation was examined comprehensively.

12.4 The Authority also recalled the decision taken in 105th meeting held on 15.12.2022 regarding suo moto correction framework wherein it was decided that action may be taken by NPPA for carrying out corrections even after the notification of prices when such errors are acknowledged by Pharmarack.

12.5 Accordingly, the revised draft working sheets were uploaded on website on 09.04.2025 for M/s Aristo Laboratories Pvt. Ltd. (Marketer) & M/s Ravenbhel Healthcare Pvt. Ltd. (Manufacturer) and M/s Macleods Pharmaceuticals Ltd. (Marketer) & M/s Ravenbhel Healthcare Pvt. Ltd. (Manufacturer) at proposed price of Rs. 14.26 per ml. The companies were also informed through emails in this respect. It was noted that no representation has been received.

12.6 Accordingly, the Authority deliberated the matter in detail and henceforth, approved the retail price of Rs. 14.26 per ml for **Each 5 ml Contains: Cholecalciferol IP 60000 IU** for M/s Aristo Laboratories Pvt. Ltd. (Marketer) & M/s Ravenbhel Healthcare Pvt. Ltd. (Manufacturer) and M/s Macleods Pharmaceuticals Ltd. (Marketer) & M/s Ravenbhel Healthcare Pvt. Ltd. (Manufacturer).

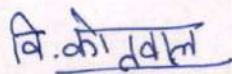
Agenda item no. 13: Form-IV intimation by M/s GlaxoSmithKline Pharmaceutical Limited (GSK) for discontinuation of the scheduled formulation viz., Grisovin FP 250mg Tablet containing Griseofulvin under para 21(2) of DPCO, 2013-reg.

13.1 The Authority noted and approved the decision to re-invoke Para 3 of the DPCO, 2013 on M/s GlaxoSmithKline Pharmaceutical Limited (GSK) for the scheduled formulation viz., Grisovin FP 250mg Tablet containing Griseofulvin, effective until 31.05.2026. The Authority also directed the company to comply with the earlier directions issued under Para 3 of the DPCO, 2013, vide letter dated 24.05.2024, considering the larger public interest.

The Authority members and the officers present in the meeting placed on record the deep appreciation for the exemplary contributions of Dr. Vinod Kotwal, Member Secretary, NPPA, who has been promoted and transferred to the Ministry of Health & Family Welfare as Additional Secretary to the Government of India. The Authority acknowledged the key role of Dr. Kotwal in major policy decisions during her tenure, COVID management and several other initiatives including, publication of the NPPA 25-year commemorative book, launch of the bi-monthly NPPA journal, implementation of IPDMS 2.0 etc. The members and officers expressed their gratitude and conveyed best wishes for success in her new assignment.

The Authority members and the officers present in the meeting also acknowledged the contributions made by Sh. Anthony Cyriac, Economic Adviser, DEA for his contributions to the Authority during his tenure upon his transfer from DEA.

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


(Dr. Vinod Kotwal)
Member Secretary