

मिसिलस.- 8(134)/2025/डी.पी/एनपीपीए-डीवी-II

F. No. 8(134)/2025/DP/NPPA-Div. II

कार्यवाहीस. : 266/134/2025/F

Proceeding No: 266/134/2025/F

Minutes of the 266th (overall) and 134th meeting of the Authority under DPCO, 2013 held on 26-06-2025 at 12:00 p.m.

The 266th meeting of the Authority (overall), which is the 134th meeting under the DPCO, 2013 was held on 26th June, 2025 at 12:00 p.m. under the Chairmanship of Shri P. Krishnamurthy, Chairman, NPPA. The following Authority members were present during the meeting:

- (i) Ms. Sai Ahlladini Panda, 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 133rd Meeting held on 29.05.2025.

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

2. Agenda item no. 2 - (a) Action Taken Report (ATR) on decisions taken by NPPA in its 133rd Meeting held on 29.05.2025.

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 72 (Seventy-two) cases of retail price fixation of new drugs as presented in Agenda no. 4 (1) to 4 (72) falling under the purview of Para 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of 71 (Seventy one) 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

Sl. 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)	Amoxycillin & Potassium clavulanate Tablets	Each Film coated tablet contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 875 mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125 mg	1 Tablet	M/s Medicef Pharma /M/s Cadila Pharmaceuticals Ltd.	41.04
2	4(2)	Aspirin Gastro-resistant & Atorvastatin Capsules	Each hard gelatin capsule contains: Aspirin IP 75mg (As Gastro-resistant Pellets) Atorvastatin Calcium IP Eqv. to Atorvastatin 10mg (As Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Alkem Laboratories Ltd.	3.65
3	4(3)	Budesonide, Glycopyrronium & Formoterol fumarate dihydrate inhalation	Each actuation delivers : Budesonide IP 200 mcg Glycopyrronium Bromide ph. Eur.eq. to Glycopyrronium 12.5 mcg Formoterol fumarate Dihydrate IP 6 mcg	1 Metered Dose	M/s Lupin Ltd.	6.11
4	4(4)	Cefixime Oral Suspension	Each 5 ml of reconstituted suspension contains: Cefixime Equivalent to Cefixime Anhydrous 200 mg	1 ml	M/s Alps Communication Pvt. Ltd./ M/s Galpha Laboratories Ltd.	3.72
5	4(5)	Ceftriaxone, Disodium Edetate & Sulbactam 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. Sulbactam 500 mg	1 vial	M/s Protech Telelinks/ M/s Tyykem Pvt. Ltd.	515.57
6	4(6)	Ceftriaxone, Disodium Edetate & Sulbactam 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. Sulbactam 1000 mg	1 vial	M/s Protech Telelinks/ M/s Tyykem Pvt. Ltd.	1036.60
7	4(7)	Combipack of Ceftriaxone, Disodium Edetate and	Each Combi-pack contains: (A) Ceftriaxone, Disodium Edetate and Sulbactam powder for solution for	1 vial	M/s BDR Pharmaceuticals International Pvt.	447.00

Sl. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
		Sulbactam powder for solution for Infusion	infusion 1.5gm Each Vial Contains: Ceftriaxone sodium IP eq. to Ceftriaxone 1000mg Disodium Edetate IP 37mg Sulbactam Sodium IP Equivalent to Sulbactam 500mg B) Sterile water for injections IP 10ml Each ampoules contains : Water for injection IP 10ml		Ltd. M/s Bluecross Laboratories Pvt. Ltd.	
8	4(8)	Combipack of Ceftriaxone, Disodium Edetate and Sulbactam powder for solution for Infusion	Each Combi-pack contains: (A) Ceftriaxone, Disodium Edetate and Sulbactam powder for solution for infusion 3.0 gm Each Vial Contains: Ceftriaxone sodium IP eq. to Ceftriaxone 2000 mg Disodium Edetate IP 74 mg Sulbactam Sodium IP Equivalent to Sulbactam 1000 mg B) Sterile water for injections IP 20 ml Each ampoules contains : Water for injection IP 20 ml	1 vial	M/s BDR Pharmaceuticals International Pvt. Ltd. M/s Bluecross Laboratories Pvt. Ltd.	626.00
9	4(9)	Cefuroxime Axetil & Potassium Clavulanate Tablets	Each Film coated tablet contains: Cefuroxime Axetil IP Eq. to Cefuroxime 500 mg Potassium clavulanate Diluted IP Eq. to Clavulanic Acid 125 mg	1 Tablet	M/s Hetero Labs Ltd./ M/s Troikaa Pharmaceuticals Ltd.	61.84
10	4(10)	Ciprofloxacin & Dexamethasone Eye /Ear Drops	Ciprofloxacin Hydrochloride IP eq. to Ciprofloxacin 0.3% w/v Dexamethasone IP 0.1% w/v Bezalkonium Chloride Solution IP 0.02 % w/v (Preservative)	1 ml	M/s Hanuchem Laboratories/ M/s Aristo Laboratories Pvt. Ltd.	2.47
11	4(11)	Combikit of Clarithromycin Tablets, Esomeprazole Tablets and Amoxicillin Tablets	Composition: Each Strip Contains: A. Clarithromycin Tablets IP 2 Tablets Each Film Coated Tablet Contains: Clarithromycin IP 500 mg B. Esomeprazole Tablets IP 2 Tablets Each enteric coated Tablet Contains: Esomeprazole Magnesium	1Kit	M/s Malik Lifesciences Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	162.52

Sl. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
			Trihydrate IP Equivalent to Esomeprazole 40 mg C. Amoxicillin Tablets USP 2 Tablets Each Film Coated Tablet Contains: Amoxycillin Trihydrate IP Equivalent to Amoxycillin 1000 mg			
12	4(12)	Diclofenac Injection	Each ml contains: Diclofenac Sodium IP 75 mg	1 ml	M/s Nitin Lifesciences Ltd. /M/s. Mankind Prime labs Ltd.	Deferred (Note 1)
13	4(13)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet Contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd./ M/s Mankind Prime Labs Pvt. Ltd.	18.10
14	4(14)	Empagliflozin & Metformin Hydrochloride (ER) Tablets	Each Film Coated Bilayered Tablet Contains: Empagliflozin 12.5mg Metformin Hydrochloride IP 1000mg (As Extended release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Blue Cross Laboratories Pvt. Ltd.	10.80
15	4(15)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet Contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd./ M/s Mankind Prime Labs Pvt. Ltd.	19.64
16	4(16)	Empagliflozin, Linagliptin & Metformin (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 & Cure Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	16.97
17	4(17)	Empagliflozin, Linagliptin & Metformin (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 & Cure Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	20.54
18	4(18)	Sitagliptin, Glimepiride & Metformin Hydrochloride tablets	Each Film Coated Tablet Contains: Glimepiride IP 1 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 50 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Torrent Pharmaceuticals Ltd.	12.98
19	4(19)	Sitagliptin, Glimepiride & Metformin Hydrochloride tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Micro Labs Ltd.	12.00

Sl. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
			Glimepiride IP 1 mg Metformin Hydrochloride IP 500 mg			
20	4(20)	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 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Intas Pharmaceuticals Ltd.	12.98
21	4(21)	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg, Glimepiride IP 1 mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Eris Lifesciences Ltd.	12.98
22	4(22)	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg, Glimepiride IP 1 mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Lupin Ltd.	12.98
23	4(23)	Sitagliptin, Glimepiride and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 1 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Mankind Pharma Ltd.	12.98
24	4(24)	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 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Torrent pharmaceuticals Ltd.	14.66
25	4(25)	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 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Micro Labs Ltd.	14.00
26	4(26)	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 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Intas Pharmaceuticals Ltd.	14.66

Sl. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
27	4(27)	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg, Glimepiride IP 2 mg, Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Lupin Ltd.	14.66
28	4(28)	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 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Mankind Pharma Ltd.	14.66
29	4(29)	Itraconazole Capsules (Supra- Bioavailable formulation)	Each hard gelatin capsule contains: Itraconazole IP 65 mg	1 Capsule	M/s Ravenbhel Healthcare Pvt. Ltd/ M/s Intas Pharmaceuticals Ltd.	11.45
30	4(30)	Levofloxacin Infusion	Each 100 ml contains: Levofloxacin Hemihydrate IP eq. to Levofloxacin 500 mg, Dextrose (Anhydrous) IP 5% w/v	1 ml	M/s Axa Parenterals Ltd./ M/s Aristo Laboratories Pvt. Ltd.	1.46
31	4(31)	Linezolid injection	Each 100ml contains: Linezolid IP 200 mg, Dextrose Anhydrous IP 5% w/v	1 ml	M/s Amanta Healthcare Ltd. / M/s Corona Remedies Pvt. Ltd.	1.60
32	4(32)	Methylprednisolone Tablets	Each uncoated tablet contains: Methylprednisolone IP 8 mg	1 Tablet	M/s Innova Captab Ltd. / M/s Troikaa Pharmaceuticals Ltd.	5.22
33	4(33)	Moxifloxacin Eye Drops	Moxifloxacin Hydrochloride IP Eq. to Moxifloxacin 0.5% w/v, Benzalkonium Chloride Solution IP 0.02% v/v (as preservative), Sterile aqueous buffered vehicle	1 ml	M/s Hanuchem Laboratories / M/s Aristo Laboratories Pvt. Ltd.	36.26
34	4(34)	Myo-Inositol, D-Chiro Inositol & Vitamin D3 Powder	Each 5g Sachet contains: Vitamin D3 (Stabilized form) 1000 IU, Myo-Inositol IP 2000 mg, D-Chiro Inositol 50 mg	1 gm	M/s Safetab Life Science/ M/s Corona Remedies Pvt. Ltd.	9.02
35	4(35)	Paracetamol bilayered sustained release tablets	Each uncoated bilayered sustained release tablet contains: Paracetamol IP (as Immediate release) 300 mg, Paracetamol IP (as sustained release) 700 mg	1 Tablet	M/s Pure and cure Healthcare Pvt. Ltd./ M/s GlaxoSmithKline Asia Pvt. Ltd.	4.71

Sl. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
36	4(36)	Paracetamol Oral Suspension	Each 5 ml Contains: Paracetamol IP 500 mg	1 ml	M/s Naxpar Pharma Pvt. Ltd./ M/s Micro Labs Ltd.	0.66
37	4(37)	Paracetamol Oral Suspension	Each 5ml contains: Paracetamol IP 500mg	1 ml	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Alkem Laboratories Ltd.	0.66
38	4(38)	Ibuprofen & Paracetamol suspension	Each 5 ml contains: Ibuprofen IP 100 mg Paracetamol IP 162.5 mg	1 ml	M/s Mascot Health Series Pvt. Ltd./ M/s Alembic Pharmaceuticals Ltd.	0.53
39	4(39)	Mefenamic Acid & Paracetamol suspension	Each 5 ml contains: Mefenamic Acid IP 100 mg Paracetamol IP 250 mg	1 ml	M/s Mascot Health Series Pvt. Ltd./ M/s Alembic Pharmaceuticals Ltd.	0.94
40	4(40)	Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Tablets	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 Aristo Laboratories Pvt. Ltd.	5.25
41	4(41)	Polmaxoxib & Paracetamol Tablets	Each uncoated tablet contains: Polmaxoxib IH 2 mg, Paracetamol IP 325 mg	1 Tablet	M/s Hetero Labs Ltd. / M/s Intas Pharmaceuticals Ltd.	15.39
42	4(42)	Aceclofenac, Paracetamol & Trypsin Chymotrypsin Tablets	Each enteric coated tablet contains: Proteolytic enzymes Trypsin & Chymotrypsin in the ratio of Approximately 6:1 and provides enzymatic activity Eq. to 1,50,000 Armour units Aceclofenac IP 100 mg Paracetamol IP 325 mg	1 Tablet	M/s Akums Drugs & pharmaceuticals Ltd / M/s Aristo Pharmaceutical Pvt. Ltd	15.18
43	4(43)	Trastuzumab for Injection	Each Lyophilized vial contains: Trastuzumab (In House) (375 mg) , α, α Trehalose dihydrate Ph. Eur. (340.91 mg) , L-Histidine HCl monohydrate Ph. Eur. (8.44 mg) , L-Histidine Ph. Eur. (5.45 mg) , Polysorbate 20 IP (1.53 mg)	1 vial	M/s Reliance Life Sciences Pvt. Ltd.	11966.64
44	4(44)	Vitamin D3 (Cholecalciferol) Drops	Each ml contains: Cholecalciferol (Vitamin D3) IP 800 IU	1 ml	M/s Indchemie Health Specialities Pvt. Ltd.	6.11
45	4(45)	Zolpidem Tartrate & Melatonin tablets	Each film coated tablet contains: Zolpidem Tartrate IP 5 mg Melatonin BP 3 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Intas	6.62

Sl. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
					Pharmaceuticals Ltd.	
46	4(46)	Phenylephrine HCl, Chlorpheniramine Maleate, Boric Acid & Hydroxypropylmethyl Cellulose Eye Drops	Composition: Phenylephrine HCl IP 0.12 %w/v Chlorpheniramine Maleate IP 0.2 % w/v Boric Acid IP 1.25 % w/v Hydroxypropylmethyl Cellulose IP 0.3 % w/v Benzalkonium Chloride IP 0.01 % w/v	1 ml	M/s Appasamy Ocular Devices Pvt. Ltd./ M/s Intas Pharmaceuticals Ltd.	7.63 (Note 2)
47	4(47)	Methylcobalamin, Alpha Lipoic Acid, Pyridoxine Hydrochloride & Folic Acid Capsules	Each hard gelatin capsule contains : Methylcobalamin IP 1500 mcg Alpha Lipoic Acid IP 100 mg Pyridoxine Hydrochloride IP 3 mg Folic Acid IP 1.5mg	1 Capsule	M/s East African(India) Overseas/ M/s Softdeal Pharmaceutical Pvt. Ltd.	14.64 (Note 3)
48	4(48)	Zolpidem Tartrate & Melatonin tablets	Each film coated tablet contains: Zolpidem Tartrate IP 10 mg Melatonin BP 3 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Intas Pharmaceuticals Ltd.	9.02 (Note 4)
49	4(49)	Myo-Inositol, D-Chiro Inositol & Vitamin D3 powder	Each 5g Sachet contains: Vitamin D3 IP (Water soluble) 1000 IU Myo-Inositol IP 2000 mg D-Chiro Inositol 50 mg	1 gm	M/s Safetab Life Science / M/s Sun Pharma Laboratories Limited	9.02
50	4(50)	Metoprolol succinate (ER), Amlodipine & Telmisartan Tablets	Each film coated bilayered tablet contains: Metoprolol Succinate IP 23.75 mg eq. to Metoprolol Tartrate 25 mg (As extended release) Amlodipine Besilate IP eq. to Amlodipine 5 mg Telmisartan IP 40 mg	1 Tablet	M/s Ajanta Pharma Ltd.	12.96
51	4(51)	Dehydroepiandrosterone (DHEA)(Micronised) & Folic Acid Capsules	Each hard gelatin capsule contains: Dehydroepiandrosterone (DHEA)(Micronised) 25 mg, Folic Acid IP 1.5 mg	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Sun Pharma Laboratories Ltd.	14.08
52	4(52)	Glycopyrronium & Formoterol Fumarate inhaler	Each actuation delivers: Glycopyrronium (As Glycopyrrolate IP) 12.5mcg Formoterol Fumarate Dihydrate IP 6mcg	1 Metered dose	M/s Cipla Ltd.	4.08
53	4(53)	Empagliflozin, Sitagliptin & Metformin	Each film coated bilayer tablet contains: Empagliflozin 10 mg, Sitagliptin Phosphate	1 Tablet	M/s Exemed Pharmaceuticals / M/s Corona Remedies Pvt. Ltd.	31.60

Sl. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
		Hydrochloride (ER) Tablets	Monohydrate IP equivalent to Sitagliptin 100 mg, Metformin Hydrochloride IP 1000 mg (as extended release)			
54	4(54)	Empagliflozin, Sitagliptin & Metformin (ER) tablets	Each Film Coated Bilayer Tablet contains: Empagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100 mg Metformin Hydrochloride IP (As Extended Release) 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	31.60
55	4(55)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each Film Coated bilayer Tablet Contains: Empagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100mg Metformin Hydrochloride IP (As Extended Release) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Alkem Laboratories Ltd.	31.60
56	4(56)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayer tablet contains: Empagliflozin 10mg Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100mg Metformin Hydrochloride IP (As extended release) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Lupin Ltd	25.00
57	4(57)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each Film Coated bilayer Tablet Contains: Empagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100mg Metformin Hydrochloride IP (As Extended Release) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Torrent Pharmaceuticals Ltd.	22.50
58	4(58)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each Film Coated bilayer Tablet Contains: Empagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100mg Metformin Hydrochloride IP (As Extended Release) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Mankind Pharma Ltd.	31.60
59	4(59)	Empagliflozin, Sitagliptin &	Each Film Coated bilayer Tablet Contains:	1 Tablet	M/s Exemed Pharmaceuticals /	25.00

Sl. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
		Metformin Hydrochloride (ER) Tablets	Empagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100mg Metformin Hydrochloride IP (As Extended Release) 1000mg		M/s Intas Pharmaceuticals Ltd.	
60	4(60)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayer tablet contains: Empagliflozin 10 mg, Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100 mg, Metformin Hydrochloride IP 1000 mg (as extended release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Ltd.	31.60
61	4(61)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayer tablet contains: Empagliflozin 10 mg, Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100 mg, Metformin Hydrochloride IP 1000 mg (as extended release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	22.00
62	4(62)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each Film Coated bilayer Tablet Contains: Empagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100mg Metformin Hydrochloride IP (As Extended Release) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Sun Pharmaceutical Industries Ltd.	26.00
63	4(63)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayer tablet contains: Empagliflozin 25 mg, Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100 mg, Metformin Hydrochloride IP 1000 mg (as extended release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	23.00
64	4(64)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayer tablet contains: Empagliflozin 25 mg, Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100 mg, Metformin Hydrochloride IP 1000 mg (as extended release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Ltd.	35.19
65	4(65)	Empagliflozin, Sitagliptin &	Each Film Coated bilayer Tablet Contains:	1 Tablet	M/s Exemed Pharmaceuticals /	35.19

Sl. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
		Metformin Hydrochloride (ER) Tablets	Empagliflozin 25mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100mg Metformin Hydrochloride IP (As Extended Release) 1000mg		M/s Mankind Pharma Ltd.	
66	4(66)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each Film Coated bilayer Tablet Contains: Empagliflozin 25 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100mg Metformin Hydrochloride IP (As Extended Release) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Torrent Pharmaceuticals Ltd.	25.00
67	4(67)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each Film Coated bilayer Tablet Contains: Empagliflozin 25 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100mg Metformin Hydrochloride IP (As Extended Release) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Sun Pharmaceutical Industries Ltd.	30.00
68	4(68)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each Film Coated bilayer Tablet Contains: Empagliflozin 25 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100mg Metformin Hydrochloride IP (As Extended Release) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	26.00
69	4(69)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each Film Coated bilayer Tablet Contains: Empagliflozin 25mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100mg Metformin Hydrochloride IP (As Extended Release) 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Alkem Laboratories Ltd.	34.00
70	4(70)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayer tablet contains: Empagliflozin 25 mg Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100mg Metformin Hydrochloride	1 Tablet	M/s Exemed Pharmaceuticals / M/s Lupin Ltd.	30.00

Sl. No.	Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
			IP (As extended release) 1000mg			
71	4(71)	Empagliflozin, Sitagliptin & Metformin (ER) tablets	Each Film Coated Bilayer Tablet contains: Empagliflozin 25 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100 mg Metformin Hydrochloride IP (As Extended Release) 1000 mg.	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	35.19
72	4(72)	Empagliflozin, Sitagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayer tablet contains: Empagliflozin 25mg, Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 100mg, Metformin Hydrochloride IP 1000mg (as extended release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Corona Remedies Pvt. Ltd.	35.19

Note1 – The Authority directed to re-examine the data and accordingly the matter was deferred.

Note 2- The Authority noted that the M/s Intas Pharmaceuticals Ltd. represented on 15.05.2025 against the draft working sheet uploaded on website stating that product "New Ocurest-AH Eye drops" is having same composition and should be included in worksheet. The matter was examined and it was observed that the referred product was launched in Nov-2024 whereas data has been considered for the period Aug-2023 to Sept 2024 for prices calculation. Hence, there is no change in the calculation. Accordingly, the Authority approved the retail price of Rs. 7.63 per ml as per draft working sheet.

Note 3- The Authority noted that the M/s Softdeal Pharmaceutical Pvt. Ltd. represented on 6.05.2025 against the draft working sheet on uploaded on website on 25.04.2025 stating that product "Nevrup OD Capsule" is having same composition and should be included in the worksheet. The matter was examined based on the confirmation from Pharmarack. It was observed that the referred product has the same composition. Accordingly, revised draft working sheet was uploaded on 16.5.2025. No representation was received against the revised draft worksheet. Accordingly, the Authority approved the retail price of Rs. 14.64 per capsule as per revised draft working sheet.

Note 4- The Authority noted that the M/s Intas Pharmaceuticals Ltd. represented on 3.06.2025 against the draft working sheet uploaded on website stating that two products "Somnisure M by Matteo Healthcare Pvt. Ltd" and "Soza-M by Gentech Healthcare Pvt. Ltd" are not included in draft worksheet. The matter was examined and it was observed that the product "Soza M" is not available in market database and if Somnisure M is considered in the working sheet, there would be no change in the proposed price as the SKU Somnisure M has less than 1% market share. Therefore, there is no change in the calculation. Accordingly, the Authority approved the retail price of Rs. 9.02 per tablet as per draft working sheet.

5. Agenda item no. 5: Minutes of 68th meeting of Multidisciplinary Committee of Experts held on 03.06.2025

5.1 Noted

6. Agenda item no. 6: Application under para 11 (3) of DPCO, 2013 for special retail price of Paracetamol and Phenylephrine Hydrochloride sachet (Each sachet containing Paracetamol I.P. 500 mg and Phenylephrine HCl I.P. 10 mg) by M/s GlaxoSmithKline Asia Private Limited.

6.1 The Authority noted that M/s GlaxoSmithKline Asia Private Limited vide email dated 18.11.2024 submitted a retail price application under Para 11(3) of DPCO, 2013 for the formulation "Paracetamol and Phenylephrine Hydrochloride sachet - Each sachet containing Paracetamol I.P. 500 mg and Phenylephrine HCl I.P. 10 mg" and claimed price of Rs. 27/- per sachet (exclusive of GST). The applicant claimed advantages like faster solubility, faster disintegration hence better safety and efficacy, better AUC level, absorption in intestine, useful in patients who have difficulty in swallowing and claimed lower price compared to other companies.

6.2 The Authority further noted that the matter was placed in 65th meeting of MDC held on 23.1.2025 wherein the Committee observed the photographs of subject formulations of other companies available in the market as provided by M/S GlaxoSmithKline Asia Private Limited which were not clear. It was noted that, the applicant gave the detailed presentation for their formulation and also submitted clear copy of packshots of other companies in the 66th meeting of MDC held on 3.3.2025.

6.3 From the packshots submitted by the applicant, it was observed that M/s Cista Medicorp (Marketer) & M/s Akums Drugs & Pharmaceuticals Ltd. (manufacturer) is already manufacturing & marketing the subject formulation under the brand name 'ENFRIO' hot sip at MRP of Rs.30 per sachet. Accordingly, the committee recommended the retail price under Para 11(3) at Rs. 6.96 per sachet as calculated based on the data of received from M/S Cista Medicorp in 68th meeting of MDC held on 03.06.2025.

6.4 The Authority deliberated upon the matter and the recommendation of MDC, and approved a separate retail price under Para 11(3) at Rs. 6.96 per sachet.

7. Agenda item no. 7: Application for approval of separate ceiling prices of IV fluids in special feature packaging by M/s Cartel Lifescience Pvt. Ltd.

7.1 The Authority noted that M/s Cartel Lifescience Pvt. Ltd. vide letter dated 20.2.2025 applied for approval of separate ceiling prices of IV fluids in special feature packaging (Special feature product in PP granules, where dual port cap is the special feature) for 8 formulations.

7.2 The Authority noted that the matter was deliberated in 67th meeting of the MDC held on 02.04.2025 and 68th meeting held on 03.06.2025. In the 68th meeting, the representative of the company requested to withdraw the application in respect of 3 formulations i.e., Dextrose Injection IP 10% w/v, Multiple Electrolytes and Dextrose Injection IP Type I (P) and Multiple Electrolytes and Dextrose Injection IP Type III (M). He also demonstrated the applied products and mentioned the special features of the products i.e. (i) self- collapsibility and self-seal ability (ii) not having air-vent and (iii) no chance of contamination during manufacture/ infusion/ admixing levels.

7.3 The Committee also noted that the applicant had claimed lower price for the formulations in comparison to separate ceiling prices notified by NPPA. Therefore, the Committee deliberated upon the matter and recommended lower of the claimed price or present applicable separate ceiling price for 5 formulations.

7.4 The Authority deliberated upon the matter and approved the recommendation of MDC to extend the lower of claimed price or present applicable separate ceiling price to the product of M/S Cartel Lifescience Pvt. Ltd. as mentioned in table below-

Sr. No.	Name of Product	Pack Size	Claimed MRP excluding GST per pack	Ceiling price applicable as on date per pack excluding GST (Rs.) w.e.f. 01.04.2025	Recommended separate price per pack excluding GST
1.	Sodium Chloride Inj 0.9% w/v	100ml	42.05	42.79	42.05
2.	Sodium Chloride Inj 0.9% w/v	500ml	87.90	89.47	87.90
3.	Compound Sodium Lactate Injection	500ml	64.96	66.09	64.29
4.	Dextrose Injection IP 5% w/v	500ml	82.24	83.70	82.24
5.	Dextrose 5% + Sodium Chloride 0.9% Inj.	500ml	85.49	87.01	85.49

8. Agenda item no. 8: Application by M/s Pulse Pharmaceuticals Private limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (iii) for the formulation "Paracetamol Oral solution (taste masked) 125mg/5ml and 250mg/5ml produced utilizing indigenously developed innovative LYOMATRIX Technology offering Novel Drug Delivery System"

8.1 The Authority noted that M/s Pulse Pharmaceuticals Private limited vide e-mail dated 24.08.2024 had applied for exemption under Para 32 (iii) for the formulation "Paracetamol Oral solution (taste masked) 125mg/5ml and 250mg/5ml produced utilizing indigenously developed innovative LYOMATRIX Technology offering Novel Drug Delivery System". The applicant had stated that Paracetamol Oral solution (taste masked)

is designed utilizing an indigenously developed innovative LYOMATRIX Technology, which has been developed at its Department of Scientific and Industrial Research (DSIR), recognized R&D unit.

8.2 The Authority also noted that the applicant had claimed that indigenously developed innovative LYOMATRIX technology, offering Novel Drug Delivery system, bioequivalence study suggesting faster absorption, randomized comparative single centre open label clinical trial suggesting faster temperature reduction, acceptability of the product in comparison to the marketed product on all parameters including taste, smell and mouth feel, very efficacious, reduced number of doses and frequency of administration for pharmacoeconomic benefit, DCGI's approval as new drug and other economic benefits.

8.3 The Authority further noted that the Paracetamol oral solution 125mg/5ml and 250mg/5ml are scheduled formulations and present applicable ceiling price is Rs. 0.38 and Rs. 0.68 per ML respectively.

8.4 The Authority recalled that the MDC in its 63rd meeting held on 22.10.2024 recommended that the proposal does not qualify under the provisions of Para 32 of the DPCO for exemption from price control as the delivery system developed by the company does not fall under the 'New Drug Delivery System' as solutions are covered under oral liquid dosage form which are already in existence. Further, there are other formulations also in the market that are taste masked. However, based on the representation dated 5.11.2024 of the applicant company, the Authority in its 128th meeting held on 12.12.2024 directed that the applicant company may be given one more opportunity to represent their case before MDC.

8.5 Accordingly, the matter was again deliberated in 65th MDC meeting held on 23.01.2025 and 68th meeting of MDC held on 03.06.2025, wherein the Committee examined the additional submissions and presentation made by the applicant. The Committee reiterated that the applied drug does not qualify for the exemption under Para 32 (iii) of the DPCO.

8.6 The Authority deliberated upon the matter in detail and approved the recommendation of the MDC rejecting the application claiming exemption under Para32(iii) for the captioned formulation.

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


(Sai Ahladini Panda)
Member Secretary