

मिसिलस.- 8(125)/2024/डी.पी/एनपीपीए-डीवी-II

F. No. 8(125)/2024/DP/NPPA-Div. II

कार्यवाहीस. : 256/125/2024/F

Proceeding No: 256/125/2024/F

Minutes of the 257th (overall) and 125th meeting of the Authority under DPCO, 2013 held on 25.07.2024 at 03:30 PM.

The 257th meeting of the Authority (overall), which is the 125th meeting under the DPCO, 2013 was held on 25th July, 2024 at 03:30PM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

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

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)
- (iv) Ms. Yuvika Panwar, Assistant Director (Pricing)

1. Agenda item no. 1 - Confirmation of Minutes of the 124th Meeting held on 07.06.2024.

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 124th Meeting held on 07.06.2024.

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 70 (seventy) cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (lxx) falling under the purview of Para 2(1)(u) of DPCO, 2013

4.2 The Authority approved the retail prices of 58(fifty-eight) new drugs under Para 5 and 15 of the DPCO 2013, as detailed in **Table 1**.

4.3 With respect to 12 (twelve) cases as given in **Table 2**, the Authority noticed that the companies have launched the formulations without obtaining price approval from NPPA. The Authority deliberated upon the worked-out price, claimed price and the launched price and approved the lowest of the three prices as the retail price of the new drugs as given in **Table 2**.

Table No. 1: Retail price fixation of new drugs

S. No.	Agenda No.	Medicines	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	4 (i)	Paracetamol Infusion IP	Each 100ml contains: Paracetamol IP 1000mg water for Injection	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd. / Dr. Reddy's Laboratories Limited	3.58
2	4 (ii)	Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine maleate Tablets	Each uncoated tablets contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 10mg Chlorpheniramine maleate IP 2mg	1 Tablet	M/s East African (India) Overseas / M/s Softdeal Pharmaceutical Private Limited	4.83
3	4 (iii)	Metoprolol Succinate (Extended Release), Amlodipine & Telmisartan Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended release form) Amlodipine Besilate IP eq. to Amlodipine 5mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Ipca Laboratories Limited	14.50
4	4 (iv)	Paracetamol Tablet IP 1000mg	Each uncoated tablet contains: Paracetamol IP 1000mg	1 Tablet	M/s Alkem Health Science (A unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Limited	4.08

S. No.	Agenda No.	Medicines	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
5	4 (v)	Ceftazidime 2gm/ Avibactam 0.5gm powder for concentrate solution for infusion	Each vial contains: Sterile Ceftazidime Pentahydrate IP eq. to Anhydrous Ceftazidime 2gm (added Sodium carbonate as buffering agent) Sterile Avibactam Sodium eq. to Avibactam 0.5gm	1 Vial	M/s GMH Organics /M/s Orchid Pharma Limited	1572.59
6	4 (vi)	Metoprolol Succinate (Extended Release), Amlodipine & Telmisartan Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended release form) Amlodipine Besilate IP eq. to Amlodipine 5mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceutical Ltd. / M/s Mankind Pharma Ltd.	14.50
7	4 (vii)	Atorvastatin and Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg Ezetimibe IP 10mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Ipca Laboratories Limited	24.74
8	4 (viii)	Omeprazole Injection	Each vial contains: Omeprazole IP (Sterile) 40mg	1 Vial	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Ltd.	40.17
9	4 (ix)	Atorvastatin and Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 40mg Ezetimibe IP 10mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Ipca Laboratories Limited	33.63
10	4 (x)	Combikit of Clarithromycin Tablets IP, Esomeprazole Tablets IP & Amoxicillin Tablets USP	Composition: Each Strip contains: A. Clarithromycin Tablets IP 2 Tablets Each film coated tablet contains: Clarithromycin IP 500mg B. Esomeprazole Tablets IP 2 Tablets Each Enteric coated tablet contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg C. Amoxicillin Tablets USP 2 Tablets Each Film coated tablet contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 1000mg	1 kit	M/s Malik Lifesciences Pvt. Ltd. / M/s Natco Pharma Limited	205.48
11	4 (xi)	Rosuvastatin and	Each film coated tablet contains:	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. /	19.00

S. No.	Agenda No.	Medicines	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Clopidogrel Tablets	Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg		M/s Torrent Pharmaceuticals Ltd.	
12	4 (xii)	Rosuvastatin and Clopidogrel Tablets	Each film coated tablet contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	15.60
13	4 (xiii)	Ceftriaxone and Sulbactam for Injection 1.5 gm	Each vial contains: Ceftriaxone Sodium IP (Sterile) eq. to Anhydrous Ceftriaxone 1000mg Sulbactam Sodium IP (Sterile) eq. to Sulbactam 500mg	1 Vial	M/s Aqua Vitoe Laboratories /M/s Orchid Pharma Limited	153.06
14	4 (xiv)	Meropenem and Sulbactam for Injection 1.5 gm	Each vial contains: Sterile Meropenem Trihydrate IP eq. to Anhydrous Meropenem 1000mg Sterile Sodium Carbonate IP Eq. to Sodium 90.2mg (as buffer) Sterile Sulbactam Sodium IP eq. to Sulbactam 500mg	1 Vial	M/s GMH Organics /M/s Orchid Pharma Limited	1620.01
15	4 (xv)	Fexofenadine Hydrochloride and Montelukast tablets	Each film coated bilayer tablet contains: Fexofenadine Hydrochloride IP 180mg Montelukast Sodium IP eq. to Montelukast 10mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Sun Pharmaceutical Industries Limited	17.90
16	4 (xvi)	Metoprolol Succinate Extended Release, Amlodipine & Telmisartan Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended release) Amlodipine Besilate IP eq. to Amlodipine 5mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Limited	14.50
17	4 (xvii)	Metoprolol Succinate Extended Release, Amlodipine & Telmisartan Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended release) Amlodipine Besilate IP eq. to Amlodipine 5mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Ltd.	14.50
18	4 (xviii)	Atorvastatin and Clopidogrel Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As pellets form),	1 Capsule	M/s Aeon Formulations Pvt. Ltd. / M/s Ipca Laboratories Limited	14.48

S. No.	Agenda No.	Medicines	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
			Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As pellets form)			
19	4 (xix)	Atorvastatin and Clopidogrel Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As pellets form), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As pellets form)	1 Capsule	M/s Aeon Formulations Pvt. Ltd. / M/s Ipca Laboratories Limited	19.05
20	4 (xx)	Calcium Citrate Malate and Vitamin D3 Tablets	Each film coated Tablet Contains: Calcium Citrate Malate IP eq. to elemental Calcium 250mg Vitamin D3 IP 1000 IU	1 Tablet	M/s Alkem Health Science (A unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Limited	11.02
21	4 (xxi)	Telmisartan and Cilnidipine tablets	Each film coated tablet contains: Telmisartan IP 40mg Cilnidipine IP 20mg	1 Tablet	M/s Macleods Pharmaceuticals Limited	14.28
22	4 (xxiv)	Cefixime and Ofloxacin Tablets	Each film coated Tablet contains: Cefixime IP eq. to Anhydrous Cefixime 200mg Ofloxacin IP 200mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Eris Healthcare Pvt. Ltd.	14.13
23	4 (xxv)	Adapalene and Benzoyl Peroxide gel	Each gram of gel contains: Adapalene 0.1% w/w Hydrous Benzoyl Peroxide eq. to Benzoyl Peroxide 2.5% w/w (as microsphere)	1 Gram	M/s Swiss Garnier Life Sciences / M/s Mankind Pharma Ltd.	21.98
24	4 (xxvi)	Cyclosporine Eye Drops	Composition: Cyclosporine IP 0.05% w/v Sterile Aqueous Vehicle	1 ml	M/s Appasamy Ocular Devices (P) Ltd. / M/s Mankind Pharma Ltd.	95.06
25	4 (xxvii)	Bisoprolol Fumarate and Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5 mg Telmisartan IP 40 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Ipca Laboratories Ltd.	9.65
26	4 (xxviii)	Bisoprolol Fumarate and Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5 mg Telmisartan IP 40 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Ipca Laboratories Ltd.	11.21
27	4 (xxix)	Cefpodoxime & Potassium Clavulanate Tablets	Each film coated tablet contains: Cefpodoxime Proxetil IP eq. to Cefpodoxime 200mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg	1 Tablet	M/s Malik Lifesciences Pvt. Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	29.21
28	4 (xxx)	Linagliptin & Metformin Hydrochloride (ER)	Each film coated bilayered tablet contains: Linagliptin 2.5mg Metformin Hydrochloride IP	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Limited	8.38

S. No.	Agenda No.	Medicines	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Tablets	500mg (as extended release)			
29	4 (xxxi)	Linagliptin and Metformin Hydrochloride Tablets	Each film coated bilayered tablet contains: Linagliptin 5mg Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s La Renon Healthcare Pvt. Ltd.	12.47
30	4 (xxxii)	Dolutegravir, Emtricitabine and Tenofovir Alafenamide Tablet	Each film coated tablet contains: Dolutegravir Sodium eq. to 50mg of Dolutegravir Tenofovir Alafenamide 25mg (eq. to 28mg of Tenofovir Alafenamide fumarate), Emtricitabine 200mg	1 Tablet	M/s APL Healthcare Ltd. / M/s Aurobindo Pharma Limited	121.21
31	4 (xxxiii)	Bisoprolol and Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5 mg Telmisartan IP 40 mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	9.65
32	4 (xxxiv)	Bisoprolol and Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5 mg Telmisartan IP 40 mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	11.21
33	4 (xxii)	Sitagliptin and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Glimepiride IP 2 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	15.27
34	4 (xxiii)	Sitagliptin and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Glimepiride IP 1 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	13.59
35	4 (xxxv)	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	13.63
36	4 (xxxvi)	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	15.31

S. No.	Agenda No.	Medicines	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
37	4 (xxxvii)	Sitagliptin, 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 Mascot Health Series Pvt. Ltd. / M/s Alembic Pharmaceuticals Limited	15.22
38	4 (xxxviii)	Sitagliptin, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Alembic Pharmaceuticals Limited	13.54
39	4 (xxxix)	Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets	Each film coated bilayer tablet contains: Linagliptin 5mg Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (as sustained release form)	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s La Renon Healthcare Pvt. Ltd.	19.43
40	4 (xl)	Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets	Each film coated bilayer tablet contains: Linagliptin 5mg Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (as sustained release form)	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s La Renon Healthcare Pvt. Ltd.	20.73
41	4 (xli)	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aprica Healthcare Limited	16.69
42	4 (xlii)	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aprica Healthcare Limited	13.68
43	4 (xliii)	Dapagliflozin, Metformin Hydrochloride (Extended Release) and	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aprica Healthcare Limited	15.36

S. No.	Agenda No.	Medicines	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Glimepiride Tablets	500mg (As Extended release) Glimepiride IP 2 mg			
44	4 (xliv)	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aprica Healthcare Limited	15.01
45	4 (li)	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg Glimepiride IP 1 mg	1 Tablet	M/s Sun Pharma Laboratories Limited	12.19
46	4 (lii)	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg Glimepiride IP 2 mg	1 Tablet	M/s Sun Pharma Laboratories Limited	13.87
47	4 (liv)	Paracetamol and Caffeine Tablets	Each uncoated tablet contains: Paracetamol IP 500mg Caffeine IP (Anhydrous) 50mg	1 Tablet	M/s Juggat Pharma (Pharma Division of Jagdale Industries Pvt. Ltd.)	2.38
48	4 (liii)	Teneligliptin, Dapagliflozin & Metformin Hydrochloride (Sustained Release) Tablets	Each film coated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	14.21
49	4 (lxi)	Ceftazidime and Avibactam powder for concentrate for solution for infusion	Each vial contains: Sterile Ceftazidime Pentahydrate IP eq. to Anhydrous Ceftazidime 2.0gm (added Sodium carbonate as buffering agent) Sterile Avibactam Sodium eq. to Avibactam 0.5gm	1 Vial	M/s GMH Organics /M/s Zyphars Pharmaceuticals Pvt. Ltd.	1572.59
50	4 (lxii)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained	Each film coated Bilayered Tablet Contain: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	14.00

S. No.	Agenda No.	Medicines	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Released) Tablet	eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 500mg (Sustained Release Form)			
51	4 (lxiii)	Glimepiride, Voglibose & Metformin Hydrochloride (Extended-release) tablet	Each uncoated Bilayered tablet contains: Glimepiride IP 2mg Voglibose IP 0.2mg Metformin Hydrochloride IP 1000mg (As Extended Release)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	14.08
52	4 (lxiv)	Glimepiride, Voglibose & Metformin Hydrochloride (Extended-release) tablet	Each uncoated Bilayered tablet contains: Glimepiride IP 1mg Voglibose IP 0.2mg Metformin Hydrochloride IP 1000mg (As Extended Release)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	11.51
53	4 (lxv)	Telmisartan, Amlodipine & Hydrochlorothiazide Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 40mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Hydrochlorothiazide IP 12.50 mg	1 Tablet	M/s Uni Medicolabs / M/s Torrent Pharmaceuticals Ltd.	10.23
54	4 (lxvi)	Telmisartan, Amlodipine & Hydrochlorothiazide Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 80mg, Amlodipine Besylate IP eq. to Amlodipine 5mg, Hydrochlorothiazide IP 12.50 mg	1 Tablet	M/s Uni Medicolabs / M/s Torrent Pharmaceuticals Ltd.	16.48
55	4 (lxvii)	Cholecalciferol Vitamin D3 Oral solution	Each 5ml contains: Cholecalciferol IP 60000 IU	1 ml	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	13.92
56	4 (lxviii)	Aspirin and Clopidogrel capsules	Each hard gelatin capsule contains: Clopidogrel Bisulphate eq. to Clopidogrel 75mg Aspirin IP (as enteric coated tablets) 75mg	1 Capsule	M/s Windlas Biotech Limited / M/s Modipharma Pvt. Ltd.	4.95
57	4 (lxix)	Bisoprolol Fumarate and Amlodipine Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5 mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Swiss Garnier Biotech Private Limited / M/s Ipca Laboratories Limited	6.23
58	4 (lxx)	Bisoprolol Fumarate and Amlodipine Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5 mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Swiss Garnier Biotech Private Limited / M/s Ipca Laboratories Limited	8.97

Table No. 2: Retail price fixation of new drugs launched without price approval

S. No.	Agenda No.	Medicines	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
59	4 (xlv)	Telmisartan and Chlorthalidone Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 40mg Chlorthalidone IP 6.25mg	1 Tablet	M/s Innova Captab Ltd./ M/s Corona Remedies Pvt. Ltd.	5.80
60	4 (xlvi)	Dapagliflozin, Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin IP 100mg (As Sustained release from) Metformin Hydrochloride IP 500mg (as Sustained Release from)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Macleods Pharmaceuticals Ltd.	13.17
61	4 (xlvii)	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as extended release)	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Unison Pharmaceuticals Pvt. Ltd.	10.27
62	4 (xlviii)	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (Extended release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as extended release)	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Unison Pharmaceuticals Pvt. Ltd.	11.16

63	4 (xl)	Teneligliptin, Dapagliflozin & Metformin Hydrochloride (Sustained Release) Tablets	Each film coated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	12.15
64	4 (l)	Teneligliptin, Dapagliflozin & Metformin Hydrochloride (Sustained Release) Tablets	Each film coated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	13.39
65	4 (lv)	Sitagliptin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s CORONA Remedies Pvt. Ltd.	12.41
66	4 (lvi)	Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (As Extended Release form)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Corona Remedies Pvt. Ltd.	14.20
67	4 (lvii)	Sitagliptin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s CORONA Remedies Pvt. Ltd.	6.49
68	4 (lx)	Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Sitagliptin Phosphate	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s	13.30

		Tablets	Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride (as Extended Release) IP 500mg		CORONA Remedies Pvt. Ltd.	
69	4 (lviii)	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as Extended Release) IP 500mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Macleods Pharmaceuticals Ltd.	15.89
70	4 (lix)	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate IP eq. to Sitagliptin 100mg Metformin Hydrochloride (as Extended Release) IP 1000mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Macleods Pharmaceuticals Ltd.	17.50

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

5.1 Noted.

6. **Agenda item no. 6 –Minutes of 60thmeeting of Multidisciplinary Committee of Experts held on 26.06.2024.**

6.1 Noted

7. **Agenda item no. 7 -Revision of ceiling prices based on Review Orders under NLEM, 2022.**

7.1 The Authority noted that the Department of Pharmaceuticals (DoP) has issued following review orders:

Table 3: Review Orders of DoP

S.No.	Review Order No. & Date	Formulation and Notification
I.	31015/19/2023-Pricing	Valganciclovir 450mg Tablet of M/s RPG Life

S.No.	Review Order No. & Date	Formulation and Notification
	dated 27.05.2024	Sciences Limited against NPPA notification S.O No. 5939(E) dated 19.12.2022
II.	31015/14/2023-Pricing dated 27.05.2024	Metoprolol 25mg tablet of M/s RPG Life Sciences Limited against S.O. 87(E) dated 06.01.2023
III.	31015/16/2023-Pricing dated 27.05.2024	Lamivudine 100mg Tablet and Montelukast 4mg tablet' of M/s Cipla Limited against NPPA notification S.O No. 5939(E) dated 19.12.2022

7.2 The Authority noted that based on the review orders, as mentioned in **Table 3** above, draft calculation sheets with revised ceiling prices were uploaded on NPPA website for comments, if any. It was noted that no representations were received for the cases mentioned at S.No I and III.

7.3 The Authority noted that in case of Metoprolol 25mg tablet mentioned at S. No II M/s Cipla Ltd filed a representation stating that Metoprolol ER 25mg tablets, which is a non-scheduled formulation has been considered in the working sheet of Metoprolol 25mg tablet. The Authority noted that in revised Schedule I (NLEM,2022) Metoprolol is listed as Metoprolol Tablet 25 mg and Metoprolol 25 mg MR/ER/SR variant is not mentioned separately. Accordingly, ceiling price is calculated based on methodology approved in this respect in 104th Authority Meeting held on 23.11.2022 by considering all variants. Further, it was also noted that the methodology is in line with practice as followed by NPPA under NLEM 2015 and NLEM 2022.

7.4 The Authority deliberated upon the matter in detail and approved the ceiling prices as mentioned in Column 5 of **Table 4** based on the review orders. It was noted that the prices have been calculated after giving effect of WPI increase of 12.1218% w.e.f. 1.04.2023 and WPI increase of (+)0.00551% w.e.f. 01.04.2024.

Table 4: Revision in Ceiling Prices based on Review Orders

S. No.	Formulation	Dosage form(s) and strength(s)	Current Ceiling Price (in Rs)	Revised Ceiling Price (in Rs) [based on review orders]	Unit
1	2	3	4	5	6
1.	Valganciclovir	Tablet 450 mg	400.73	408.27	1 tablet
2.	Metoprolol	Tablet 25mg	4.20	4.25	1 tablet
3.	Lamivudine	Tablet 100mg	10.40	11.07	1 tablet
4	Montelukast	Tablet 4 mg	10.03	10.23	1 tablet

8. **Agenda item no. 8 -Request for continuation of retail prices approved & notified by NPPA for M/s Sun Pharma Laboratories Limited in respect of formulations "Each film coated bilayered tablet contains Telmisartan IP 40mg, Chlorthalidone IP 6.25mg and Metoprolol Tartrate (as extended release) 25mg/50mg".**

8.1 The Authority noted that M/s Sun Pharma Laboratories Limited vide letter dated 04.06.2024 requested NPPA to permit marketing of following two formulations at prices approved by NPPA notified vide S.O. No.5423(E) dated 28.12.2021 while shifting the manufacturing of the said formulations to its own site at Sikkim from M/s Ravenbhel Healthcare Private Limited:

- (i) Each film coated bilayered tablet contains Telmisartan IP 40mg, Chlorthalidone IP 6.25mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg
- (ii) Each film coated bilayered tablet contains Telmisartan IP 40mg, Chlorthalidone IP 6.25mg, Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg

8.2 The Authority noted that applicant has made the above request to ensure uninterrupted availability of both the products to the patients. The Authority recalled that the guidelines for allowing the marketing companies to continue marketing the already launched formulation with a new manufacturer have been determined in 115th meeting held on 31.07.2023. One of the conditions is "shifting of manufacturing to its own plant by the existing marketing entity."

8.3 The Authority deliberated upon the matter in detail and noted that in the instant case since M/s Sun Pharmaceuticals Ltd. has applied for the manufacture at its own site, and the company may be permitted to market the said formulations at NPPA approved retail price not exceeding the present applicable retail price.

9. **Agenda item no. 9- Review petition of M/s VHB Life Sciences Limited against NPPA's notification S.O. No. 194(E) dated 11.01.2023 pertaining to Artamin 250 mg capsule 10's containing Penicillamine 250 mg capsule (Ref: DoP letter No. 31015/32/2023-Pricing dated 16.06.2023)**

9.1 The Authority noted that the working sheet related to the fixation of ceiling price of the formulation Penicillamine 250mg capsule under NLEM, 2022 was uploaded on NPPA's website on 13.12.2022 for 10 working days to invite comments, if any. No representation was received for the same. Hence, the ceiling price of Rs. 13.96 per capsule was approved in the 107th Authority meeting held on 11.01.2023 and notified vide S.O. No. 194(E) dated 11.01.2023.

9.2 M/s VHB Life Sciences Limited filed a review petition under Para 31 of DPCO, 2013 requesting for consideration of correct Price-to-Retailer (PTR) of their brand after

implementation of WPI under Para 16 of DPCO 2013 in the month of April, 2022. The petitioner has submitted Form II and Form V on 16.04.2022 as per DPCO, 2013 requirements.

9.3 The matter was examined and DoP vide letter dated 01.05.2023 was informed that the company had not filed any representation to NPPA in 10 working days of uploading of the draft worksheet. Hence, the PTR available in market database was considered while fixing the ceiling price.

9.4 DoP through its review order No. 31015/32/2023 dated 28.05.2024 gave following directions:

"In the backdrop of these facts, the contention regarding fixation of price of 'Artamin 250mg capsule 10's containing Penicillamine 250mg' without considering the revised PTR in absence of representation is accepted. Accordingly, the case is referred back to NPPA for recalculation of the prices of the subject formulation as per the extant provisions of DPCO, 2013".

9.5 The matter was examined by the Authority and it was found that although Form-II for the year 2022 has been filed by M/S VHB Life Sciences Ltd. within the timelines as mentioned in DPCO i.e. on 16.04.2022. However, Form II for previous four years i.e., 2018 to 2021 were filed on 8.3.2022 i.e., not within the time limit prescribed under DPCO, 2013. The Authority took note of the following details with respect to Form II filed by M/S VHB Life Sciences Ltd.:

Table 5: Date of submission of Form-II by M/S VHB Life Sciences Ltd.

Name of the product	Pack size	Pack	PTR	Revised PTR	WPI change	Ceiling price notified	Effective date	Date of Form II submission
ARTAMIN 250MG (D Penicillamine Caps.)	10	20	2204	2279.2	3.44	2790	01.04.2018	08.03.2022
ARTAMIN 250MG (D Penicillamine Caps.)	10	20	2279.2	2376	4.27	2910	01.04.2019	08.03.2022
ARTAMIN 250MG (D Penicillamine Caps.)	10	20	2376	2420.78	1.88	2964	01.07.2020	08.03.2022
ARTAMIN 250MG (D Penicillamine Caps.)	10	1	2420.78	2433.6	0.54	2980	01.04.2021	08.03.2022
ARTAMIN 250MG (D Penicillamine Caps.)	10	20	2433.6	2695.6	10.77	3300	01.04.2022	16.04.2022

9.6 The Authority deliberated up on the matter in terms of Para 16 (2) and 16 (3) of DPCO 2013 which reads as below:

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"(2) The manufacturers may increase the maximum retail price (MRP) of scheduled formulations once in a year, in the month of April, on the basis of the wholesale price index with respect to previous calendar year and no prior approval of the Government in this regard shall be required.

(3) Information about the revision, if carried out, shall be forwarded to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision and non-submission of information under this sub-paragraph shall be construed as non revision of maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the pre-revised maximum retail price (MRP), along with interest thereon from the date of overcharging."

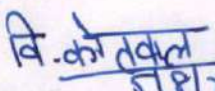
9.7 The Authority observed that DoP has directed to recalculate the prices of the subject formulation as per the extant provisions of DPCO, 2013. M/S VHB Lifesciences Ltd. has contravened Para 16 (3) of DPCO, 2013 in filing Form II during the 2018-2021 and hence, PTR revisions in these years are invalid. Consequently, the PTR revision in April, 2022 is also invalid and cannot be considered for ceiling price fixation, although Form II has been filed within the prescribed timelines. Thus, keeping in view the DPCO, 2013 provisions, the Authority decided that the PTR as appearing in July, 2022 market database should be considered for fixing the ceiling price.

9.8 The Authority noted that recalculated ceiling price based on PTR of July 2022 would be same as earlier notified price. Since, no change in recalculated ceiling price is observed, hence no fresh notification is needed.

10. Agenda item no. 10: Invoking of Para 3 of DPCO 2013 on M/S Concept Pharmaceuticals Ltd. for supply of Rifampicin 450 mg. Capsules

10.1 The Authority deliberated upon the matter in detail and noted the decision of invoking Para 3 of DPCO, 2013 to direct M/s Concept Pharmaceutical Limited for the supply of Rifampicin 450 mg capsule to the Rajasthan Medical Services Corporation Limited (RMSCL), as per the reported prices/ceiling prices as applicable until the supply of the quantity assigned to the company by RMSCL.

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


(Dr. Vinod Kotwal)
Member Secretary