

मिसिलस.- 8(110)/2024/डी.पी/एनपीपीए-डीवी-II
F. No. 8(121)/2024/DP/NPPA-Div. II

कार्यवाहीस. : 253/121/2024/F
Proceeding No: 253/121/2024/F

Minutes of the 253rd(overall) and 121stmeeting of the Authority under DPCO, 2013 held on 20.02.2024 at 03:00 PM.

The 253rd meeting of the Authority (overall), which is the 121st meeting under the DPCO, 2013 was held on 20th February, 2024 at 03:00 PM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

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

Shri Ranga Chandrashekar, Deputy Drugs Controller, CDSCO, Ministry of Health & Family Welfare was also present.

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

- (i) Shri Sanjay Kumar, Advisor (Cost-I)
- (ii) Shri. G.L Gupta, Director (M&E)
- (iii) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (iv) Shri. Mahaveer Saini, Deputy Director (Pricing)
- (v) Shri. Rajesh Kumar T, Deputy Director (M&E)
- (vi) Ms. Yuvika Panwar, Assistant Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 120th Meeting held on 24.01.2024.

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 120th Meeting held on 24.01.2024.

2.1 The Authority noted the Action Taken Report on the decision taken in 120th Meeting. With respect to action taken in r/o decision taken by Authority in r/o agenda item no. 10, it was noted that no feedback has been received from the Authority Members. The matter was deliberated and it was decided that since no feedback has

been received the matter may be treated as closed and NPPA may continue the on-going practice in line with recommendation of the MDC.

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

3.1 Noted.

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

4.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (iv) (b) (total 70 Form I applications containing retail price fixation of 70 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 70 (Seventy) new drugs under Para 5 and 15 of the DPCO 2013, as detailed in **Table 1**:

Table No. 1: Retail price fixation of new drugs

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (i)	Sitagliptin and Metformin Hydrochloride Extended Release Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (As extended release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	13.25
4 (ii)	Olmesartan Medoxomil, Amlodipine & Hydrochlorothiazide Tablet	Each film coated tablet contains: Olmesartan Medoxomil IP 20mg Amlodipine Besilate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Blue Cross Laboratories Private Limited	8.92
4 (iii)	Olmesartan Medoxomil, Amlodipine & Hydrochlorothiazide Tablet	Each film coated tablet contains: Olmesartan Medoxomil IP 40mg Amlodipine Besilate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Blue Cross Laboratories Private Limited	10.71

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Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (iv)	Telmisartan, Amlodipine & Hydrochlorothiazide Tablet	Each film coated tablet contains: Telmisartan IP 80mg Amlodipine Besilate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	16.24
4 (v)	Paracetamol, Phenylephrine HCl & Chlorpheniramine Maleate Syrup	Each 5ml contains: Paracetamol IP 125mg Phenylephrine HCl IP 5.0mg Chlorpheniramine Maleate IP 1.0mg	1 ml	M/s Mascot Health Series Pvt. Ltd. / M/s Biological E. Limited	1.06
4 (vi)	Phenylephrine Hydrochloride and Chlorpheniramine Maleate Syrup	Each 5ml contains: Phenylephrine Hydrochloride IP 5.0mg Chlorpheniramine Maleate IP 2.0mg	1 ml	M/s Windlas Biotech Limited / M/s Biological E. Limited	1.22
4 (vii)	Chlorpheniramine Maleate, Dextromethorphan Hydrobromide & Phenylephrine Hydrochloride Syrup	Each 5ml contains: Chlorpheniramine Maleate IP 2mg Phenylephrine Hydrochloride IP 5mg Dextromethorphan Hydrobromide IP 15mg	1 ml	M/s Yacca Lifesciences Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	0.94
4 (viii)	Escitalopram Oxalate Tablets	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 15mg	1 Tablet	M/s Lupin Limited	11.84
4 (ix)	Amoxicillin and Potassium Clavulanate Oral Suspension	Each 5ml of reconstituted suspension contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 400mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 57mg	1 ml	M/s Brooks Laboratories Ltd. / M/s German Remedies Pharmaceuticals Private Limited	4.22
4 (x)	Cefixime and Ofloxacin Tablets	Each film coated tablet contains: Cefixime IP (As Trihydrate) eq. to Anhydrous Cefixime 200mg Ofloxacin IP 200mg	1 Tablet	M/s Aagya Biotech Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	13.87
4 (xi)	Paracetamol Paediatric Oral Suspension	Each 1ml contains: Paracetamol IP 100mg	1 ml	M/s Aristo Pharmaceuticals Pvt. Ltd.	1.62



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (xii)	Chlorpheniramine Maleate, Dextromethorphan Hydrobromide & Phenylephrine Hydrochloride Syrup	Each 5ml contains: Chlorpheniramine Maleate IP 2mg Phenylephrine Hydrochloride IP 5mg Dextromethorphan Hydrobromide IP 10mg	1 ml	M/s Yacca Lifesciences Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	0.99
4 (xiii)	Clopidogrel & Aspirin Tablets	Each uncoated bilayered tablet contains: Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg Aspirin IP 150mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	4.85
4 (xiv)	Meropenem and Sulbactam for Injection	Each vial contains: Meropenem IP eq. to Anhydrous Meropenem 1000mg (A Sterile Mixture of meropenem & Sodium Carbonate (Sodium 90.2mg) Sulbactam Sodium IP eq. to Anhydrous Sulbactam 500mg	1 Vial	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	1598.75
4 (xv)	Olmesartan Medoxomil, Hydrochlorothiazide & Amlodipine Tablet	Each film coated tablet contains: Olmesartan Medoxomil IP 20mg Hydrochlorothiazide IP 12.5mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	14.52
4 (xvi)	Cefpodoxime & Potassium Clavulanate Oral suspension	Each 5ml reconstituted suspension contains: Cefpodoxime Proxetil IP eq. to Anhydrous Cefpodoxime 50mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 31.25mg	1 ml	M/s Saitech Medicare Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	3.10
4 (xvii)	Cefuroxime Axetil & Potassium Clavulanate Tablets	Each film coated tablet contains: Cefuroxime Axetil IP eq. to Cefuroxime 500mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg	1 Tablet	M/s Saitech Medicare Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	56.98



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (xviii)	Telmisartan & Chlorthalidone Tablet	Each uncoated bi-layer tablet contains: Telmisartan IP 80mg Chlorthalidone 6.25mg	1 Tablet	M/s Aristo Pharmaceuticals Pvt. Ltd.	17.74
4 (xix)	Trypsin, Bromelain, Rutoside Trihydrate and Diclofenac Sodium Tablets	Each enteric coated tablet contains: Trypsin BP 48mg Bromelain 90mg Rutoside Trihydrate BP 100mg Diclofenac Sodium IP 50mg	1 Tablet	M/s Synokem Pharmaceutical Ltd./ M/s Intas Pharmaceuticals Ltd.	21.80
4 (xx)	Montelukast and Acebrophylline (SR) Tablets	Each uncoated bilayered tablet contains: Montelukast Sodium IP eq. to Montelukast 10mg Acebrophylline 200mg (As sustained release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Apex Laboratories Private Limited	17.54
4 (xxi)	Atorvastatin and Fenofibrate Tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg Fenofibrate IP 160mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	15.93
4 (xxii)	Calcium & Vitamins Tablet	Each film coated tablet contains: Calcium Carbonate IP (From Coral Grains) eq. to Elemental Calcium 500mg Vitamin D3 IP (As Stabilised) 2000 IU Methylcobalamin IP 1500mcg L-Methylfolate Calcium USP 1mg Pyridoxal 5 Phosphate 20mg	1 Tablet	M/s Premier Nutraceuticals Pvt. Ltd. / M/s Zuventus Healthcare Limited	18.87
4 (xxiii)	Cefpodoxime & Potassium Clavulanate Tablets	Each film coated tablet contains: Cefpodoxime Proxetil IP eq. to Anhydrous Cefpodoxime 200mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg	1 Tablet	M/s Saitech Medicare Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	28.49



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (xxiv)	Levetiracetam Extended-release Tablets	Each film coated Extended-release tablet contains: Levetiracetam IP 1000mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Ltd.	33.37
4 (xxv)	Aceclofenac and Paracetamol tablets	Each film coated tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg	1 Tablet	M/s Stedman Pharmaceuticals Pvt. Ltd.	5.14
4 (xxvi)	Linagliptin and Metformin Hydrochloride Tablet	Each film coated tablet contains: Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	8.56
4 (xxvii)	Paracetamol, Phenylephrine HCl & Chlorpheniramine Maleate Tablets	Each uncoated tablet contains: Paracetamol IP 500mg Phenylephrine HCl IP 10mg Chlorpheniramine Maleate IP 2mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Private Limited	3.57
4 (xxviii)	Moxifloxacin hydrochloride & Dexamethasone Phosphate Eye Drops	Composition: Moxifloxacin hydrochloride IP eq. to Moxifloxacin 0.5%w/v Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1% w/v	1 ml	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	23.27
4 (xxix)	Trypsin-Chymotrypsin, Paracetamol and Aceclofenac Tablets	Each Film Coated Tablet contains: 150000 Armour Units Enzymatic Activity (Supplied By a Purified Concentrate Which Has Specific Trypsin & Chymotrypsin Activity In a Ratio Of Approximately Six To One) (As Enteric Coated Granules) Paracetamol IP 325 mg Aceclofenac IP 100 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Troikaa Pharmaceuticals Limited	14.21
4 (xxx)	Chlorpheniramine Maleate & Phenylephrine Hydrochloride	Each 5ml contains: Chlorpheniramine Maleate IP 2mg Phenylephrine	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Apex	1.22

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Syrup	Hydrochloride IP 5mg		Laboratories Private Limited	
4 (xxxi)	Vildagliptin and Metformin Hydrochloride Tablet	Each film coated tablet contains: Vildagliptin IP 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	8.43
4 (xxxii)	Vildagliptin and Metformin Hydrochloride Tablet	Each film coated tablet contains: Vildagliptin IP 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	8.04
4 (xxxiii)	Sitagliptin Phosphate 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 Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	9.13
4 (xxxiv)	Sitagliptin Phosphate 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 Skymap Pharmaceuticals Pvt. Ltd. / M/s German Remedies Pharmaceuticals Private Limited	10.39
4 (xxxv)	Methylcobalamin, Alpha Lipoic Acid, Vitamin D3, Pyridoxine Hydrochloride & Folic Acid Tablets	Each film coated tablet contains: Methylcobalamin IP 1500mcg Alpha Lipoic Acid IP 100mg Vitamin D3 IP 1000IU Pyridoxine Hydrochloride IP 3mg Folic Acid IP 1.5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Blue Cross Laboratories Private Limited	8.03
4 (xxxvi)	Tranexamic Tablets	Each film coated tablet contains: Tranexamic Acid IP 1000mg	1 Tablet	M/s Emcure Pharmaceuticals Limited	30.06
4 (xxxvii)	Ceftriaxone and Sulbactam injection	Each combi pack contains: Part-I Ceftriaxone and	1 Vial	M/s East African (India) Overseas / M/s	Deferred (Note 1)

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Sulbactam for Injection IP 1.5g Each vial contains: Ceftriaxone Sodium IP (Sterile) eq. to anhydrous Ceftriaxone 1000mg, Sulbactam Sodium IP (Sterile) eq. to Sulbactam 500mg Part-II Sterile water for injection IP (10ml) (SWFI For Reconstitution) Each FFS Ampoule contains: Sterile Water for Injection IP 10ml		SoftdealPharmaceuticals Private Limited	
4 (xxxviii)	Ceftriaxone and Tazobactam injection	Each combi pack contains: Part-I Ceftriaxone and Tazobactam for Injection 1125mg Each vial contains: Ceftriaxone Sodium IP (Sterile) eq. to Ceftriaxone 1gm, Tazobactam Sodium IP (Sterile) eq. to Tazobactam 125mg Part-II (For Reconstitution) Each FFS Ampoule contains: Sterile Water for Injection IP 10ml	1 Vial	M/s East African (India) Overseas / M/s Softdeal Pharmaceuticals Private Limited	189.45
4 (xxxix)	Telmisartan & Cilnidipine Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg Cilnidipine IP 10mg	1 Tablet	M/s Windlas Biotech Ltd. (Plant 2) / M/s Emcure Pharmaceuticals Limited	10.39
4 (xl)	Diclofenac Sodium & Paracetamol Tablets	Each uncoated tablet contains: Diclofenac Sodium IP 50mg,	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Softdeal	4.99

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Paracetamol IP 325mg		Pharmaceuticals Private Limited	
4 (xli)	Vitamin D3 (Cholecalciferol) Oral Drops	Each ml contains: Vitamin D3 (Cholecalciferol) 800IU	1 ml	M/s SAF Fermion Limited	5.53
4 (xlii)	Telmisartan & Chlorthalidone Tablet	Each film coated tablet contains: Telmisartan IP 40mg Chlorthalidone 6.25mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	5.35
4 (xliii)	Telmisartan & Chlorthalidone Tablet	Each film coated tablet contains: Telmisartan IP 40mg Chlorthalidone 12.50mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	6.25
4 (xliv)	Itraconazole Capsules 130mg (Supra-Bioavailable Formulation)	Each hard gelatin capsule contains: Itraconazole BP 130mg	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	19.50
4 (xlv)	Linagliptin, Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayered tablet contains: Linagliptin 5mg Metformin Hydrochloride IP 500mg (As Extended Release)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	13.03
4 (xlvi)	Linagliptin, Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayered tablet contains: Linagliptin 5mg Metformin Hydrochloride IP 1000mg (As Extended Release)	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Mankind Pharma Limited	14.65
4 (xlvii) a	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	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Eris Lifesciences Limited	14.65

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		release) Glimepiride IP 1 mg			
4 (xlvii) b	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 Mankind Pharma Ltd.	14.44
4 (xlvii) c	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 Alkem Laboratories Limited	14.65
4 (xlvii) d	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 Torrent Pharmaceuticals Limited	14.65
4 (xlvii) e	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 Lupin Limited	14.44
4 (xlvii) f	Dapagliflozin, Metformin Hydrochloride	Each film coated bilayered tablet contains:	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s	14.44



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	(Extended Release) and Glimepiride Tablets	Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 1 mg		Medley Pharmaceuticals Ltd.	
4 (xlviii) a	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 Eris Lifesciences Limited	16.33
4 (xlviii) b	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 Mankind Pharma Ltd.	16.12
4 (xlviii) c	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 Alkem Laboratories Limited	16.33
4 (xlviii) d	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	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 Torrent Pharmaceuticals Limited	16.33

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		1000mg (As Extended release) Glimepiride IP 2 mg			
4 (xlviii) e	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 Lupin Limited	16.12
4 (xlviii) f	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 Medley Pharmaceuticals Ltd.	16.12
4 (xlix) a	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	12.00
4 (xlix) b	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Alkem Laboratories Limited	13.35
4 (xlix) c	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	13.00



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Hydrochloride IP 1000mg Glimepiride IP 1 mg			
4 (l) a	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Cipla Ltd.	14.00
4 (l) b	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Alkem Laboratories Limited	15.03
4 (l) c	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	15.00
4 (liv)	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 Torrent Pharmaceuticals Limited	13.24 (Note 2)
4 (lv) a	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	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 Torrent Pharmaceuticals Limited	14.75 (Note 2)



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		500mg (As Extended release) Glimepiride IP 2 mg			
4 (iv) b	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 Alkem Laboratories Limited	14.92
4 (li)	Trypsin, Bromelain, Rutoside Trihydrate and Diclofenac Sodium Tablets	Each enteric coated tablet contains: Trypsin BP 48mg Bromelain 90mg Rutoside Trihydrate BP 100mg Diclofenac Sodium IP 50mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Neon Laboratories Limited	21.80
4 (lii)	Diclofenac Diethylamine, Methyl Salicylate & Menthol Topical Spray	Composition: Diclofenac Diethylamine IP 2.32% w/w (eq. to Diclofenac Sodium 2% w/w), Methyl Salicylate IP 10% w/w, Menthol IP 5% w/w	1 gram	M/s Pontika Aerotech Limited / M/s Cadila Pharmaceuticals Ltd.	3.12
4 (liii)	Tranexamic Acid Tablet	Each film coated tablet contains: Tranexamic Acid IP 250mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Sun Pharmaceutical Industries Limited	18.43

Note 1: Communication dated 20.02.2024 received from the company is under examination and accordingly, the matter was deferred.

Note 2: The Authority was intimated that a representation dated 13.02.2024 has been received from M/S Torrent Pharma for revision in PTR of few line items appearing in the draft working sheet. However, the same was not considered as the price has been calculated based on Pharmatrac data of June 2023 figures i.e., month ending 6 months prior to receipt of application (January 2024) and revised PTR of the line items as claimed by the company is reflected from July 2023 in Pharmatrac. Further, there is no

provision to consider derived PTR i.e., MRP -16%, as mentioned by M/S Torrent Pharma in its representation.

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

5.1 Noted

6. Agenda item no. 6 –Form-IV Intimation by M/s Neon Laboratories Limited in respect of scheduled formulation Tropine 1ml Injection (Atropine Sulphate Injection 0.6mg/ml) under para 21(2) of DPCO, 2013.

6.1 The Authority deliberated upon the matter in detail and decided to re-invoke Para 3 of DPCO 2013 in public interest since M/s Neon Laboratories Limited is having substantial market share in respect of scheduled formulation Tropine 1ml Injection (Atropine Sulphate Injection 0.6mg/ml). The Authority decided that the company M/s Neon Laboratories Limited shall be directed to maintain the production and sales of Tropine 1ml Injection (Atropine Sulphate Injection 0.6mg/ml) at current level beyond 29.02.2024 for a period of one year i.e., **up to 28.02.2025**.

7. Agenda item no. 7 –Submission of Form -IV intimation for discontinuation of 4 scheduled formulation viz., (i) Urografin 76%-20ml (ii) Urografin 76%-50ml (iii) Urografin 76%-100ml and (iv) Urografin 60%-20ml by M/s Bayer Zydus Pharma under para 21(2) of DPCO, 2013 -reg.

7.1 The Authority noted the decision taken in its 107th Authority meeting held on 11.01.2023 to invoke the Para-3 of DPCO, 2013 valid up to 29.02.2024 considering the recommendations of the 8th meeting of the Committee on Discontinuation held on 06.12.2022 in larger public interest.

7.2 The Authority deliberated upon the matter in detail and decided to re-invoke Para 3 of DPCO, 2013 to direct M/s Bayer Zydus Pharma to continue the production and sales of the subject scheduled formulations (1) Urografin 76%-20ml (ii) Urografin 76%-50ml (iii) Urografin 76%-100ml and (iv) Urografin 60%-20ml for a period of one year i.e. **up to 28.02.2025** and to ensure the production is not reduced by more than 25% of the production level at the time of discontinuation application.

8. Agenda item no. 8 –Fixation of Ceiling Price of 35 scheduled formulations under Revised Schedule-I (NLEM, 2022).

8.1. The Authority noted that ceiling price of 700 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, 111th and 112th meeting of the Authority held on 23.11.2022, 29.03.2023 and 01.05.2023 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.

8.2 The Authority noted that based on approved methodology, ceiling prices for 35 formulations were uploaded on NPPA website on 05.02.2024 for 10 working days to invite comments in compliance to O.M. No. F. NO. 31015/44/2016-PI.I dated 11.07.2016 issued by Department of Pharmaceuticals based on database of October 2023 & month of October 2023.

8.3 The Authority was informed that NPPA has received representations for correction in PTR; pack size; change of category from MDI to DPI; and consideration of plain tablets and enteric coated tablets. The Authority noted that these claims/representations have been cross verified with the Form-II/Form-V submitted by the companies till 15.05.2023 as per provisions of DPCO, 2013.

8.4 The Authority deliberated upon the ceiling price fixation and approved the ceiling prices of 31 scheduled formulations as mentioned in **Table 2** below-

Table 2: Ceiling Price fixation

S.No.	Section of Schedule-I of DPCO,2013	Formulations	Dosage form (s) and strength (s)	Prevailing Ceiling price	New Ceiling Price	Unit
(1)	(2)	(3)	(4)	(5)	(7)	(8)
1	6	Darunavir (A) +Ritonavir(B)	Tablet600mg(A)+Tablet100 mg(B)	New	146.45	1 Tablet
2	6	Zidovudine	Tablet300 mg	17.75	13.59	1 Tablet
3	23	Nicotine (for nicotine replacement therapy)	Oral Dosage forms 2mg Pastille	New	7.12	1 Pastille
4	23	Nicotine (for nicotine replacement therapy)	Oral Dosage forms 4mg Pastille	New	7.83	1 Pastille
5	6	Benzathine benzylpenicillin	Powder for Injection 12 lac units	22.70	19.81	1 Vial
6	8	Folic Acid	Capsule 5 mg	7.02	5.04	1 Capsule
7	18	Levonorgestrel	Tablet 1.5mg	New	75.35	1 Tablet
8	2	Fentanyl	Injection50mcg/mL	28.27	20.96	1 ML
9	6	Benzathine benzylpenicillin	Powder for Injection 6 lac units	15.01	11.69	1 Vial
10	17	Hyoscine butylbromide	Injection20mg/mL	12.99	11.24	1 ML

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S.No.	Section of Schedule-I of DPCO,2013	Formulations	Dosage form (s) and strength (s)	Prevailing Ceiling price	New Ceiling Price	Unit
(1)	(2)	(3)	(4)	(5)	(7)	(8)
11	17	Omeprazole	Capsule 40 mg	6.14	5.67	1 Capsule
12	26	Cholecalciferol	Solid oral dosage form 1000 IU Sachet/Granuels/Powder	New	23.14	1 GM
13	4	Desferrioxamine	Powder for injection 500mg	200.19	188.64	1 Vial
14	6	Tenofovir Disproxil Fumarate +Lamivudine+Dolu tegravir	Tablet 300mg+300mg + 50 mg	New added	114.98	1 Tablet
15	4	Snake venom antiserum	Lyophilized polyvalent -As licensed	693.71	665.22	1 Vial of 10ml
16	4	Snake venom antiserum	Soluble/ liquid polyvalent -As licensed	538.70	428.65	1 Vial of 10ml
17	7	Chlorambucil	Tablet 2 mg	45.95	31.16	1 Tablet
18	7	Melphalan	Tablet 2 mg	122.13	91.33	1 Tablet
19	7	Melphalan	Tablet 5 mg	209.48	86.04	1 Tablet
20	7	Chlorambucil	Tablet 5 mg	103.25	77.21	1 Tablet
21	7	Arsenic trioxide	Injection1mg/ mL	67.60	30.54	1 ML
22	7	5-Fluorouracil	Injection 250mg/5mL	2.90	2.04	1 ML
23	10	Acetylsalicylic acid	Conventional / Effervescent/ Dispersible/ Enteric coated Tablets 325 mg	0.68	0.67	1 Tablet (Note 1)
24	24	Budesonide	Inhalation (MDI) 100mcg/dose	1.58	1.41	1 Metered Dose
25	24	Budesonide	Inhalation (MDI) 200mcg/dose	2.20	2.03	1 Metered Dose
26	24	Budesonide	Inhalation (DPI) 200mcg/dose	3.60	3.33	1 Dose
27	16	Budesonide	Nasal Spray 100mcg/dose	1.13	0.81	1 Dose
28	24	Budesonide (A) +Formoterol(B)	Inhalation (MDI) 100mcg(A)+6 mcg(B)	2.34	2.12	1 Metered

S.No.	Section of Schedule-I of DPCO,2013	Formulations	Dosage form (s) and strength (s)	Prevailing Ceiling price	New Ceiling Price	Unit
(1)	(2)	(3)	(4)	(5)	(7)	(8)
						Dose
29	24	Budesonide (A) +Formoterol(B)	Inhalation (DPI) 100mcg(A)+6 mcg(B)	4.72	4.32	1 Dose
30	24	Budesonide (A) +Formoterol(B)	Inhalation (DPI)200mcg(A)+6 mcg(B)	6.27	5.72	1 Dose
31	24	Budesonide (A) +Formoterol(B)	Inhalation (DPI)400mcg(A)+6 mcg(B)	8.01	6.62	1 Dose

Note 1 : The Authority noted that in the draft working sheet, only the section i.e., 10.5.1 has been mentioned without mentioning the complete description. It was directed that while notifying the ceiling price, complete description of the formulation may be mentioned.

8.5 The Authority deferred the ceiling price fixation of following four formulations for the reasons cited in the Table 3 below:

Table 3: Deferred formulations

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling	Uploaded Ceiling Price	Reasons
1	7	Imatinib	Capsule400mg	317.99	91.46	The single company appearing in the worksheet represented that the formulation is Tablet. Hence, no line item left to be considered for price fixation.
2	6	Rifampicin	Tablet 300mg	3.66	3.64	The single company appearing in the worksheet represented that the formulation is Capsule. Hence, no line item left to be considered for price fixation.
3	24	Budesonide (A) +Formoterol(B)	Inhalation (MDI)200mcg(A)+6 mcg(B)	3.33	2.87	Representations received under examination
4	24	Budesonide (A) +Formoterol(B)	Inhalation (MDI)400mcg(A)+6 mcg(B)	3.80	3.01	

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

वि. कोटवाल
24/2/2024
(Dr. Vinod Kotwal)
Member Secretary