

मिसिलस.- 8(124)/2024/डी.पी/एनपीपीए-डीवी-II

F. No. 8(124)/2024/DP/NPPA-Div. II

कार्यवाहीस. : 256/124/2024/F

Proceeding No: 256/124/2024/F

Minutes of the 256th (overall) and 124th meeting of the Authority under DPCO, 2013 held on 07.06.2024 at 03:30 PM.

The 256th meeting of the Authority (overall), which is the 124th meeting under the DPCO, 2013 was held on 7th June, 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 Antony Cyriac, Economic Advisor, Department of Economic Affairs

Other officers present were:

Shri K.K. Mahawar, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure as a representative from O/o Chief Adviser (Cost).

Shri Ranga Chandrashekar, Deputy 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 G.L. Gupta, Director (M&E)
- (ii) Shri Kumar Aman Bharti, Director (OC)
- (iii) Ms. Rashmi Tahiliani, Director (Pricing)
- (iv) Shri R. Jegan, Director (OC)
- (v) Shri. Mahaveer Saini, Deputy Director (Pricing)
- (vi) Ms. Yuvika Panwar, Assistant Director (Pricing)

1. Agenda item no. 1 - Confirmation of Minutes of the 123rd Meeting held on 10.05.2024.

1.1 The Authority confirmed the minutes. However, it was noted that there was a typographical error in the Para 4.2 of minutes dated 14.05.2024 with respect to Agenda item no. 4(xxxv) mentioned in Table 2. The formulation "Each 5 ml contains Cholecalciferol IP **60000 IU** (in Nano Droplet form)" was inadvertently mentioned as "Each 5 ml contains Cholecalciferol IP **600000 IU** (in Nano Droplet form)" and the same was notified at Sr. No 2 of notification No. 199(E) dated 15.05.2024. Accordingly, the

Authority noted that the formulation has to be correctly read as “**Each 5 ml contains Cholecalciferol IP 60000 IU (in Nano Droplet form)**” and accordingly a corrigendum notification may be issued in this respect.

2. Agenda item no. 2 – (a) Action Taken Report (ATR) on decisions taken by NPPA in its 123rd Meeting held on 10.05.2024.

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 discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (xxxvi) (total 54 Form I applications containing retail price fixation of 54 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 54 (Fifty-four) new drugs under Para 5 and 15 of the DPCO 2013, as detailed in **Table 1 & Table 2:**

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)a	Linagliptin, Dapagliflozin and 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 Alkem Laboratories Ltd.	20.78
4 (i)b	Linagliptin, Dapagliflozin and 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 Torrent Pharmaceuticals Ltd.	19.00
4 (i)c	Linagliptin,	Each film coated bilayer	1	M/s Theon	20.78

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Dapagliflozin and Metformin Hydrochloride (SR) Tablets	tablet contains: Linagliptin 5mg Dapagliflozin Propanediol Monohydrate USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (as sustained release form)	Tablet	Pharmaceuticals Ltd. / M/s Zydus Healthcare Ltd.	
4 (i)d	Linagliptin, Dapagliflozin and 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 Micro Labs Limited	15.89
4 (i)e	Linagliptin, Dapagliflozin and 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 MSN Laboratories Pvt. Ltd.	19.64
4 (i)f	Linagliptin, Dapagliflozin and 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 Lupin Limited	20.78
4 (i)g	Linagliptin, Dapagliflozin and 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 Mankind Pharma Limited	20.78

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)h	Linagliptin, Dapagliflozin and 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 Intas Pharmaceuticals Ltd.	20.78
4 (i)i	Linagliptin, Dapagliflozin and 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 Torrent Pharmaceuticals Ltd.	18.00
4 (i)j	Linagliptin, Dapagliflozin and 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 Alkem Laboratories Ltd.	19.64
4 (i)k	Linagliptin, Dapagliflozin and 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 Zydus Healthcare Ltd.	19.64
4 (i)l	Linagliptin, Dapagliflozin and 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 MSN Laboratories Pvt. Ltd.	18.75

Handwritten signature/initials

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		release form)			
4 (i)m	Linagliptin, Dapagliflozin and 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 Intas Pharmaceuticals Ltd.	19.64
4 (i)n	Linagliptin, Dapagliflozin and 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 Micro Labs Limited	15.00
4 (i)o	Linagliptin, Dapagliflozin and 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 Mankind Pharma Limited	19.64
4 (i)p	Linagliptin, Dapagliflozin and 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 Lupin Limited	19.64
4 (ii)a	Glimepiride & Sitagliptin Tablet	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 Mankind Pharma Limited	15.38
4 (ii)b	Glimepiride & Sitagliptin Tablet	Each film coated tablet contains:	1 Tablet	M/s Exemed Pharmaceuticals	15.38

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Glimepiride IP 2 mg		/ M/s Eris Lifesciences Limited	
4 (ii)c	Glimepiride & Sitagliptin Tablet	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 Mankind Pharma Limited	13.70
4 (ii)d	Glimepiride & Sitagliptin Tablet	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Glimepiride IP 1mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Limited	13.70
4 (iii)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin IP 100mg (As Sustained release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Aristo Pharmaceuticals Pvt. Ltd.	13.78
4 (iv)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin IP 100mg (As Sustained release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Aristo Pharmaceuticals Pvt. Ltd.	15.27
4 (v)	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 Mascot Health Series Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	12.86

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (vi)	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 Mascot Health Series Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	14.65
4 (vii)	Bisoprolol Fumarate and Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5 mg Telmisartan IP 40 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Limited	9.65
4 (viii)	Bisoprolol Fumarate and Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5 mg Telmisartan IP 40 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Limited	11.21
4 (ix)	Bictegravir, Emtricitabine & Tenofovir Alafenamide Tablets	Each film coated tablet contains: Bictegravir Sodium eq. to Bictegravir 50mg Emtricitabine IP 200mg Tenofovir Alafenamide Fumarate IP eq. to Tenofovir Alafenamide 25mg	1 Tablet	M/s Hetero Labs Limited / M/s Emcure Pharmaceuticals Limited	132.58
4 (x)	Omeprazole + Domperidone Tablets	Each gastro-resistant tablet contains: Omeprazole Magnesium BP eq. to Omeprazole 20mg Domperidone IP 10mg	1 Tablet	M/s Next Wave (India) / M/s Mankind Prime Labs Pvt. Ltd.	3.85
4 (xi)	Ceftriaxone and Sulbactam Injection	Each vial contains: Ceftriaxone Sodium IP eq to Ceftriaxone 250mg Sulbactam Sodium IP eq to Sulbactam 125mg	1 Vial	M/s Zen Pharma (P) Limited / M/s Hetero Healthcare Ltd.	58.90
4 (xii)	Ceftriaxone and Sulbactam Injection	Each vial contains: Ceftriaxone Sodium IP eq to Ceftriaxone 1000mg Sulbactam Sodium IP eq to Sulbactam 500mg	1 Vial	M/s Zen Pharma (P) Limited / M/s Hetero Healthcare Ltd.	143.92
4 (xiii)	Tranexamic Acid and Mefenamic Acid Tablets	Each film coated tablet contains: Tranexamic Acid IP 500mg Mefenamic Acid IP 250mg	1 Tablet	M/s Aagya Biotech Pvt. Ltd. / M/s J. B. Chemicals & Pharmaceuticals Ltd.	30.43

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (xiv)	Donepezil Hydrochloride and Memantine Tablets	Each film coated tablet contains: Donepezil Hydrochloride IP 10mg Memantine IP 10mg	1 Tablet	M/s Savi Health Science / M/s Alkem Laboratories Ltd.	19.11
4 (xv)	Calcium & Vitamins D3 Tablet	Each film coated tablet contains: 1.25g of Calcium Carbonate from an organic source (Oyster shell) eq. to Elemental Calcium 500mg Cholecalciferol IP (Vitamin D3) 500IU (as stabilized form)	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Sun Pharmaceutical Industries Limited	7.82
4 (xvi)	Amoxycillin and Potassium Clavulanate Oral Suspension IP	Each 5ml of the reconstituted suspension contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 600mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg	1 ml	M/s ALPS Communication Pvt. Ltd. / M/s Galpha Laboratories Ltd.	3.17
4 (xvii)	Calcitriol, Calcium & Zinc Softgel capsule	Each soft Gelatin Capsule contains: Calcium Carbonate IP 500mg eq. to Elemental Calcium 200mg Calcitriol IP 0.25mcg Zinc Sulphate Monohydrate IP eq. to Elemental Zinc 7.5mg	1 Capsule	M/s Titanium Technologies (India) Pvt. Ltd. / M/s J.B. Chemicals & Pharmaceuticals Ltd.	15.94
4 (xviii)	Mupirocin and Sucralfate Ointment	Composition: Mupirocin IP 2% w/w Sucralfate IP 7% w/w	1 gram	M/s Stedman Pharmaceuticals Pvt. Ltd.	17.05
4 (xix)	Cefixime & Ofloxacin for Oral Suspension	Each 5ml of the reconstituted suspension contains: Cefixime Trihydrate IP eq. to cefixime Anhydrous 50mg Ofloxacin IP 50mg (This pack contains 20ml of sterile water for reconstitution)	1 ml	M/s Theon Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	1.90
4 (xx)	Dextromethorphan Hydrobromide, Chlorpheniramin	Each film coated tablet contains: Dextromethorphan Hydrobromide IP 10mg	1 Tablet	M/s J.K. Print Pack (Pharma Division) / M/s Cadila	4.69

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	e Maleate & Phenylephrine Hydrochloride Tablets	Chlorpheniramine Maleate IP 2mg Phenylephrine Hydrochloride IP 5mg		Pharmaceuticals Ltd.	
4 (xxi)	Telmisartan, Chlorthalidone & Cilnidipine tablets	Each film coated tablet contains: Telmisartan IP 40mg Chlorthalidone IP 6.25mg Cilnidipine IP 10mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Indchemie Health Specialities Pvt. Ltd.	14.07
4 (xxii)	Tranexamic Acid Sustained Release Tablets	Each sustained release film coated tablet contains: Tranexamic Acid IP 750mg	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	19.09
4 (xxiii)	Atorvastatin & Aspirin Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As granules), Aspirin (As Gastro-resistant tablet IP) IP 75mg	1 Capsule	M/s Unison Pharmaceuticals Pvt. Ltd.	2.68
4 (xxiv)	Itraconazole Capsules 130mg (Supra-Bioavailable Formulation)	Each hard gelatin capsule contains: Itraconazole IP 130mg	1 Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	19.73
4 (xxv)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	Each film coated Bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 500mg (Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	14.00
4 (xxvi)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	Each film coated Bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	15.32

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Pioglitazone 15 mg Metformin Hydrochloride IP 1000mg (Sustained Release Form)			
4 (xxvii)	Clindamycin & Nicotinamide Gel	Composition: Clindamycin Phosphate IP eq. to Clindamycin 1.0% w/w Nicotinamide IP 4.0% w/w	1 Gram	M/s Pharma Force Labs / M/s Cadila Pharmaceuticals Ltd.	5.35
4 (xxviii)	Lidocaine & Prilocaine Gel	Composition: Lidocaine IP 2.50% w/w Prilocaine IP 2.50% w/w Sorbic acid IP (as preservative) 0.08% w/w	1 Gram	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Ra-Vish Wellness Pvt. Ltd.	11.39
4 (xxix)	Moxifloxacin Hydrochloride & Dexamethasone Eye Drops	Composition: Moxifloxacin Hydrochloride BP eq. to Moxifloxacin 0.5% w/v Dexamethasone Sodium Phosphate IP 0.1% w/v	1 ml	M/s Aurolab	14.00
4 (xxx)	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 Torrent Pharmaceuticals Ltd.	14.50
4 (xxxi)	Escitalopram Oxalate Tablets	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 15mg	1 Tablet	M/s Merrill Pharma Pvt. Ltd. / M/s Alkem Laboratories Limited	12.39

4.2 It was noted by the Authority that in the following five cases given in table no. 2 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 below:

rk.

Table No. 2: 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 (xxxii)	Telmisartan, Chlorthalidone and Cilnidipine Tablet	Each film coated tablet contains: Telmisartan IP 40mg Cilnidipine IP 10mg Chlorthalidone IP 6.25mg	1 Tablet	M/s Corona Remedies Pvt. Ltd.	7.14
4 (xxxiii)	Telmisartan and Chlorthalidone Tablet	Each film coated tablet contains: Telmisartan IP 40mg Chlorthalidone IP 6.25mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s La Renon Healthcare Pvt. Ltd.	7.28
4 (xxxiv)	Telmisartan and Amlodipine Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 40mg Amlodipine Besilate IP eq. Amlodipine 5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s La Renon Healthcare Pvt. Ltd.	7.31
4 (xxxv)	Telmisartan and Cilnidipine Tablet	Each film coated tablet contains: Telmisartan IP 40mg Cilnidipine IP 10mg	1 Tablet	M/s Corona Remedies Pvt. Ltd.	5.90
4 (xxxvi)	Telmisartan, Hydrochlorothiazide and Amlodipine Tablets	Each uncoated bilayered tablet contains: Telmisartan IP 40mg Hydrochlorothiazide IP 12.5mg Amlodipine Besylate eq. to Amlodipine 5mg	1 Tablet	M/s Corona Remedies Pvt. Ltd.	4.50

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

5.1 Noted

6. Agenda item no. 6 –Minutes of 59thmeeting of Multidisciplinary Committee of Experts held on 08.05.2024.

6.1 Noted

7. Agenda item no. 7 –Approval for ceiling price of different dosage forms and strength of I.V Fluids with packaging in non-glass with special features dated 24.04.2023 being filed by M/s Aculife Healthcare Pvt. Ltd.



7.1 The Authority noted the application filed by M/s Aculife Healthcare Pvt. Ltd vide letter dated 24.04.2023 for extension of separate ceiling prices for the formulations mentioned in Table 3 below with packaging in non-Glass container in plastic bottle with EUROHEAD having special features like (a) Aseptic Blow Fill Seal (ABFS) process (b) Low Density Polyethylene Plastic (c) self- sealability (d) self-collapsibility and (e) Precise Pressure Dosing System.

Table No. 3: Formulations applied by M/s Aculife Healthcare Pvt. Ltd

S. No	Medicines	Dosage form and strength	Pack size
1	Dextrose (Glucose)	Injection (25% w/v)	100 ml/500ml pack With special feature with euro head
2	Mannitol	Injection 20%	100 ml /350 ml pack With special feature with euro head
3	Metronidazole	Injection (0.5% w/v)/500mg/100ml	100ml With special feature with euro head
4.	Ciprofloxacin	Injection 200mg/100mL	100ml With special feature with euro head

7.2 The Authority noted that the matter was deliberated in 52nd, 53rd, 55th, 56th, 57th & 59th meetings of the MDC held on 11.07.2023, 08.08.2023, 17.10.2023, 20.12.2023, 27.02.2024 & 08.05.2024 respectively. It was noted by the Authority that the documents submitted by the applicant were examined by the MDC in detail and that matter had to be deliberated in several MDC meetings as the applicant was unable to furnish the complete and correct declaration with respect to the IP standards.

7.3 The Authority noted that NPPA has fixed special ceiling price of Dextrose (Glucose Injection 25% w/v) and Mannitol Injection 20% on per ML basis for the pack size of 100ml only. However, the company has applied for separate ceiling price for 500ml pack for Dextrose (Glucose Injection 25% w/v) and 350ml pack for Mannitol Injection 20% in addition to 100ml pack. It was noted that the MDC had recommended to extend the present applicable separate ceiling prices to these pack sizes also in addition to 100 ml pack size

7.4 It was further noted that separate ceiling price for special feature packaging for the formulation Ciprofloxacin Injection 200mg/100ml has not been fixed for any company yet. However, the MDC has recommended a separate ceiling price for the formulation Ciprofloxacin Injection 200mg/100ml in non glass special feature container with euro head at Rs.0.23 per ml i.e. 15% over the present applicable ceiling price of Ciprofloxacin Injection 200mg/100ml for M/S Aculife Healthcare Pvt. Ltd.



7.5 The Authority deliberated upon the matter in detail and accepted the recommendation of MDC. Accordingly, the Authority extended/fixed the special ceiling prices of formulations to M/s Aculife Healthcare Pvt. Ltd as mentioned in Table 4 below-

Table No. 4: Details of ceiling prices under Para 11(3)

S.No	Medicines	Dosage form and strength	Unit	Ceiling price (wef 01.04.2024 with WPI @0.00551%)
1	Dextrose (Glucose)	Injection (25% w/v)	100 ml pack With special feature with euro head	0.24 per ml as notified vide S.O 1557(E) dated 26.03.2024
2	Dextrose (Glucose)	Injection (25% w/v)	500ml pack With special feature with euro head	
3	Mannitol	Injection 20%	100 ml pack With special feature with euro head	0.40 per ml as notified vide S.O 1556(E) dated 26.03.2024
4.	Mannitol	Injection 20%	350ml pack With special feature with euro head	
5	Metronidazole	Injection (0.5% w/v)/ 500mg/100 ml	100ml With special feature with euro head	0.25 per ml as notified vide S.O 1555(E) dated 26.03.2024
6	Ciprofloxacin	Injection 200mg/100ml	100ml With special feature with euro head	0.23 per ml i.e (0.20 per ML notified vide S.O 1547(E) dated 26.03.2024 + 15% on account of special packaging)

8. Agenda item no. 8 -Application for extension of ceiling price of I.V Fluids with packaging in non-glass with special feature by M/s Puniska Injectables Private Limited in line with relevant pricing notification under para 11(3) of DPCO,2013.

8.1 The Authority noted the application filed by M/s Puniska Injectables Private Limited vide letter 27.05.2023 and 07.12.2023 for extension of separate ceiling price of formulations mentioned in Table 5 below having special features like "(i) self-collapsibility and self- sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels:

Table No. 5: Formulations applied by M/s Puniska Injectables Private Limited

S. No.	Product Name	Pack Size
1	Sodium Chloride 0.9%	1000 ML, 500 ML, 250ML & 100 ML

2	Glucose 5% + Sodium chloride 0.9% (DNS)	1000 ML & 500 ML
3	Glucose Injection 5% (5D)	1000 ML & 500 ML
4	Ringer Lactate	500 ML & 250 ML
5	Metronidazole Injection 0.5% w/v	100 ML

8.2 The Authority noted that the matter was deliberated in 56th & 57th meeting of MDC held on 20.12.2023 & 27.02.2024 respectively in which the product was demonstrated by the applicant and the Committee examined the documents submitted by the applicant. The Authority also noted the recommendation of the MDC to extend the current applicable separate ceiling price for eleven formulations (as mentioned in Table above) in special packaging having special features to M/s Puniska Injectables Private Limited.

8.3 The Authority deliberated upon the matter in detail and accepted the recommendations of MDC and decided to extend the special ceiling prices of 11 formulations to M/s Puniska Injectables Private Limited as mentioned in Table 6 below-

Table No. 6: Details of ceiling prices under Para 11(3)

S. No	Medicines	Dosage form and strength	Unit	Ceiling price (wef 01.04.2024 with WPI @0.00551%)
1	Glucose	Injection 5%	1000ml non-Glass with special features	95.11 S.O 1552(E) dated 26.03.2024
2	Glucose	Injection 5%	500ml non-Glass with special features	82.27 S.O 1552(E) dated 26.03.2024
3	Glucose (A) + Sodium Chloride (B)	Injection 5% (A) + 0.9% (B)	1000ml non-Glass with special features	99.94 S.O 1552(E) dated 26.03.2024
4	Glucose (A) + Sodium Chloride (B)	Injection 5% (A) + 0.9% (B)	500ml non-Glass with special features	85.52 S.O 1552(E) dated 26.03.2024
5	Sodium Chloride	Injection 0.9%	100ml non-Glass with special features	42.06 S.O 1552(E) dated 26.03.2024
6	Sodium Chloride	Injection 0.9%	250ml non-Glass with special features	62.10 S.O 1552(E) dated 26.03.2024
7	Sodium Chloride	Injection 0.9%	500ml non-Glass with special features	87.94 S.O 1552(E) dated 26.03.2024
8	Sodium Chloride	Injection 0.9%	1000ml non-Glass with special features	98.51 S.O 1552(E) dated 26.03.2024
9	Ringer lactate	Injection 500 ml	Each 500 ml pack	64.96

S. No	Medicines	Dosage form and strength	Unit	Ceiling price (wef 01.04.2024 with WPI @0.00551%)
			having special features	S.O 1553(E) dated 26.03.2024
10	Ringer lactate	Injection 250 ml	Each 250 ml pack having special features	50.99 S.O 1553(E) dated 26.03.2024
11	Metronidazole	Injection (0.5%w/v) /500mg/100ml in 100ml pack for packages in non-glass container in plastic bottle with euro head having special features	Per ml	0.25 S.O 1555(E) dated 26.03.2024

9. **Agenda item no. 9 Application to fix a separate Ceiling Price under Paragraph 11(3) of DPCO-2013, of a Scheduled formulation of Amoxicillin 200 mg + Clavulanic acid 28.5 mg Suspension in a Dual Chamber Pack with Novel Technology, being introduced in India for the first time. -Seeking additional Price for Dual Chamber Pack over and above Existing Ceiling Price – reg.**

9.1 The Authority noted the application filed by M/s Sun Pharmaceuticals Industries Limited on 29.09.2023 for fixation of separate ceiling price for scheduled formulation of Amoxicillin 200 mg + Clavulanic acid 28.5 mg suspension in a Dual Chamber Pack with Novel Technology under para 11(3) of DPCO, 2013. It was noted that the current applicable ceiling price of this formulation is Rs 2.02 per ml and that additional price of Rs.0.34 per ml over the ceiling price has been sought by the applicant on account of novel pack, dose accuracy, hygiene, better efficacy, lesser reconstitution time and no spillage while administering the drug.

9.2 The Authority noted that the matter was deliberated in 56th, 57th& 59th meeting of the MDC held on 20.12.2023, 27.02.2024& 08.05.2024 respectively. The representatives of the company gave detailed presentation before the MDC in the 57th meeting held on 27.02.2024 and also attended the 59th MDC meeting through video conferencing.

9.3 The Authority also noted that the applicant was asked by MDC in the 57th meeting to submit the Published literature / clinical study / evidence that the dual

chamber pack helps in reducing the clinical error or improved compliance as claimed by the applicant. However, the applicant stated that this kind of novel pack is not available anywhere in the world, therefore no published literature on this novel pack is available nationally or internationally and submitted a self-commissioned survey report dated 28.06.2023. The MDC in the 59th meeting examined the submissions made by the applicant and observed that there is no data / evidence in the survey report that shows reduction in reconstitution time and spillage as claimed and applicant has not provided any evidence/supporting documents towards improved efficacy of the product due to innovative packaging. Accordingly, the MDC recommended rejecting the application.

9.4 The Authority deliberated upon the matter in detail and accepted the recommendation of MDC and accordingly rejected the application of company.

10. Agenda item no. 10. Application received for special Retail price of “Flagyl Gel with Soft Tip Applicator” under Para 11(3) of DPCO 2013 for incremental innovation.

10.1 The Authority noted that retail price for the formulation “Chlorhexidine Gluconate solution IP eq. to Chlorhexidine 1% w/w + Metronidazole Benzoate IP eq. to metronidazole 1% w/w + Lignocaine Hydrochloride 2%w/w gel” has already been fixed for M/s Abbott Healthcare Pvt. Ltd. at Rs. 3.75 per gm vide SO No. 2123 (E) dated 04.05.2023. Now M/s Abbott Healthcare Pvt. Ltd. has applied for special price under para 11(3) on account of Incremental Innovation for the same formulation titled as **“Flagyl Gel with Soft Tip Applicator” under para 11(3) of DPCO, 2013** vide application dated 25.10.2023. The Authority noted that the applicant has claimed the special features like hands free application, targeted application, mitigating cross contamination & spreading of bacteria, non messy and controlled dispensing and improved compliance as the special features of the product. The applicant has also mentioned that the design of Soft Tip Applicator has been registered with the Office of CGPTD. It was noted that the applicant has claimed additional cost of Rs. 25/- per **Soft Tip Applicator + Shoulder +Cap.**

10.2 The Authority further noted that the matter was deliberated in 56th, 57th & 59th meeting of MDC held on 20.12.2023, 27.02.2024 & 08.05.2024 respectively. The representatives of the company gave detailed presentation before the 57th MDC wherein applicant was asked to submit following with respect to their claim by the MDC:

- i. Published literature/ clinical study/ evidence that the applicator helps in administering the drug to improve the compliance of patients, compared to the same drug without the applicator.
- ii. If the evidence for the benefit of the applicator is only in a subset of patients, the company may provide this detail.

Yk.

- iii. Comments regarding whether the applicator would be classified as a medical device
- iv. The quantum of the residual drug in the applicator.
- v. Why this applicator needs to be sold with the drug itself? It is more like additional/optional package item that can be sold separately.
- vi. Data with respect to bacterial load on multiple usage duly supported with clinical data

10.3 The Authority noted that the Committee examined the submissions made by the applicant vide letter dated 02.04.2024 and it was held that the applicant had submitted Patent application filed for European & US Patent but did not submit any Published literature/ clinical study/ evidence in support of the claim. The MDC also did not find the report titled "A Day on the Field with our Sales force (Oro Care)" submitted by the company as satisfactory.

10.4 Further, the Authority noted that the applicant has informed MDC that the applicator is designed to create a "drug-device combination". Accordingly, MDC stated that a 'drug-device combination' is a new drug for which a separate license is required as per NDCT rules 2019. However, the applicant has not submitted the same. Accordingly, the MDC deliberated upon the submissions of the company and rejected the claim

10.5 The Authority deliberated upon the matter in detail and decided to accept the recommendation of MDC and accordingly rejected the application of company.

11. Agenda item no. 11. Request for continuation of retail prices approved & notified by NPPA for M/s Sun Pharma Laboratories Limited in respect of formulations "Each film coated tablet contains Olmesartan Medoxomil IP 20mg/40mg, Chlorthalidone IP 12.5mg and Amlodipine 5mg".

11.1 The Authority noted that M/s Sun Pharma Laboratories Limited vide letter dated 09.04.2024 requested NPPA to permit marketing of following two formulations at prices approved by NPPA vide S.O. No.5635(E) dated 02.11.2018 while shifting the manufacturing of the said formulations to its own site at Guwahati from M/s Synokem Pharmaceuticals Limited:

- (i) Each film coated tablet contains Olmesartan IP 20mg, Chlorthalidone IP 12.5mg and Amlodipine 5mg at Rs. 9.15 per tablet
- (ii) Each film coated tablet contains Olmesartan IP 40mg, Chlorthalidone IP 12.5mg and Amlodipine 5mg at Rs. 16.19 per tablet

11.2 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 where such change is permitted is "shifting of manufacturing to its own plant by the existing marketing entity."

11.3 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, the company may be permitted to market the said formulations at NPPA approved retail price not exceeding the present applicable retail price.

12. Agenda item no. 12 Proposal for issuance of one reminder to be incorporated in existing internal guidelines dated 07.10.2016-regarding

12.1 The agenda regarding the proposal for issuance of one reminder to be incorporated in existing guidelines dated 07.10.2016 was apprised by the officials of NPPA before the Authority members. After detailed discussion on the agenda, the authority agreed to the proposals of issuing a reminder in respect of following cases, viz.,

- (i) Cases where Show Cause Notice (with quantification) needs to be issued based on examination of the Company's earlier reply wherein overcharging was denied and the said reply was submitted atleast 2 years prior to the month & year in which it is being processed to next stage/step as per internal guidelines dated 07.10.2016;
- (ii) Cases where Demand Notice needs to be issued based on examination of the Company's earlier reply wherein overcharging was denied and the said reply was submitted atleast 2 years prior to the month & year in which it is being processed to next stage/step as per internal guidelines dated 07.10.2016; and
- (iii) Cases which are to be referred to the District Collector based on examination of the Company's earlier reply wherein overcharging was denied and the said reply was submitted atleast 2 years prior to the month & year in which it is being processed to next stage/step as per internal guidelines dated 07.10.2016.

Three weeks' time will be given to the company to respond, from the date of issue of this reminder.

13. Agenda item no. 13 Invoking Para-3 of DPCO, 2013 on M/s Macleods Pharmaceuticals Ltd. for the supply of Rifampicin 150mg capsule and 450 mg capsule.

13.1 The Authority deliberated upon the matter in detail and noted the decision of invoking Para 3 of DPCO, 2013 to direct **M/s Macleods Pharmaceuticals Ltd.** for the supply of Rifampicin 150mg capsule and 450 mg capsule to the Central Medical Services

Society (CMSS), New Delhi as per the reported prices/ceiling prices as applicable for the supply of the quantity assigned to the company by CMSS.

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

वि. कोतवाल
12/6/2024
(Dr. Vinod Kotwal)
Member Secretary