

मिसिलस.- 8(114)/2023/डी.पी/एनपीपीए-डीवी-II
F. No. 8(114)/2023/DP/NPPA-Div. II

कार्यवाहीस. : 246/114/2023/F

Proceeding No: 246/114/2023/F

Minutes of the 246th(overall) and 114thmeeting of the Authority under DPCO, 2013 held on 19.06.2023 at 03:00 PM.

The 246th meeting of the Authority (overall), which is the 114th meeting under the DPCO, 2013 was held on 19th June, 2023 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 A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare was also present.

1.1 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, Jt. Director (Pricing)
- (iii) Shri R Jegan, Jt. Director (Medical Devices)
- (iv) Shri Mahaveer Saini, Deputy Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 113th Meeting held on 26.05.2023.

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 113th Meeting held on 26.05.2023.

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 (xiii) (total 52 Form I applications containing retail price fixation of 52 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013

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and approved the retail prices of 51(fifty one) new drugs under Para 5 and 15 of the DPCO 2013, as detailed in **Table 1** below:

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)	Ciprofloxacin & Dexamethasone Eye Drops	Composition: Ciprofloxacin Hydrochloride IP eq. to Ciprofloxacin 0.3% w/v Dexamethasone IP 0.1% w/v Benzalkonium Chlorid Sodium IP 0.02% v/v (As preservative) Sterile aqueous Vehicle q.s.	1 ml	M/s Skymap Healthcare Pvt. Ltd. / M/s Healing Pharma India Pvt. Ltd.	2.05
4 (ii)	Paracetamol, Phenylephrine and Chlorpheniramine Drops	Each ml (approximately 30 drops) contains: Paracetamol IP 125mg Phenylephrine Hydrochloride IP 2.5mg Chlorpheniramine Maleate IP 1.0mg	1 ml	M/s Cris Pharma (I) Ltd.. / M/s Mankind Prime Labs Pvt. Ltd.	4.15
4 (iii)	Ceftazidime and Avibactam powder for concentrate for solution for infusion	Each vial contains: Ceftazidime Pentahydrate IP eq. to Ceftazidime 2.0gm Avibactam Sodium eq. to Avibactam 0.5gm	1 ml	M/s Protech Telelinks / M/s Samarth Life Sciences Pvt. Ltd.	Deferred (Note 1)
4 (iv)	Paroxetine Controlled release & Clonazepam Capsules	Each hard gelatine capsule contains: Paroxetine Hydrochloride IP eq. to Paroxetine 25mg (As enteric coated controlled release tablet) & Clonazepam IP 0.5mg (as immediate release tablet)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Limited / M/s Eris Lifesciences Limited	15.81
4 (v)	Etoricoxib and Paracetamol Tablets	Each Film Coated tablet contains: Etoricoxib IP 60 mg Paracetamol IP 325 mg	1 Tablet	M/s Pfizer Limited	8.99
4 (vi)	Linagliptin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Linagliptin IP 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Intas Pharmaceuticals Ltd.	8.97
4 (vii)	Linagliptin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Linagliptin IP 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Intas Pharmaceuticals Ltd.	9.60
4 (viii)	Linagliptin and Metformin Hydrochloride	Each film coated tablet contains: Linagliptin IP 2.5mg	1 Tablet	M/s Torrent Pharmaceuticals Ltd.	8.90

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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)
	Tablets	Metformin Hydrochloride IP 500mg			
4 (ix)	Linagliptin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Linagliptin IP 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Torrent Pharmaceuticals Ltd.	9.50
4 (x)	Linagliptin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Linagliptin IP 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	8.97
4 (xi)	Linagliptin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Linagliptin IP 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	9.60
4 (xii) (A) (i)	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Wockhardt Limited	16.95 (Note 2)
4 (xii) (A) (ii)	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (as Extended Release) Tablets	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Wockhardt Limited	17.84 (Note 2)
4 (xii) (A) (iii)	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (As an Extended release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	19.57 (Note 2)
4 (xii) (A) (iv)	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (ER) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	20.67 (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)
		Metformin Hydrochloride IP 1000mg (As an Extended release form)			
4 (xii) (A) (v)	Dapagliflozin, Sitagliptin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Sun Pharma Laboratories Limited	13.63 (Note 2)
4 (xii) (A) (vi)	Dapagliflozin, Sitagliptin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Sun Pharma Laboratories Limited	14.60 (Note 2)
4 (xii) (B) (i)	Dapagliflozin, Vildagliptin (SR) and Metformin Hydrochloride (SR) 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 Alkem Laboratories Ltd.	18.76 (Note 2)
4 (xii) (B) (ii)	Dapagliflozin, Vildagliptin (SR) and Metformin Hydrochloride (SR) 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 Alkem Laboratories Ltd.	19.87 (Note 2)
4 (xii) (B) (iii)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Extended Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin IP (As Sustained release) 100mg Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Limited	16.18 (Note 2)
4 (xii) (B) (iv)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin IP (As Sustained	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Limited	17.04 (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)
	Extended Release) Tablets	release) 100mg Metformin Hydrochloride IP 1000mg (as Sustained Release)			
4 (xii) (B) (v)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Extended Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	16.18 (Note 2)
4 (xii) (B) (vi)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Extended Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Emcure Pharmaceuticals Limited	17.04 (Note 2)
4 (xii) (B) (vii)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Mankind Pharma Ltd.	20.11 (Note 2)
4 (xii) (B) (viii)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Mankind Pharma Ltd.	19.00 (Note 2)
4 (xii) (B) (ix)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	12.50 (Note 2)
4 (xii) (B) (x)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained	1 Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	15.00 (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)
	Sustained Release) Tablets	release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg			
4 (xii) (B) (xi)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	16.04 (Note 2)
4 (xii) (B) (xii)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Limited	16.98 (Note 2)
4 (xii) (B) (xiii)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Alembic Pharmaceuticals Limited	19.11 (Note 2)
4 (xii) (B) (xiv)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	14.90 (Note 2)
4 (xii) (B) (xv)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Unison Pharmaceuticals Pvt. Ltd.	16.44 (Note 2)
4 (xii) (B) (xvi)	Dapagliflozin, Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin IP 100mg (As	1 Tablet	M/s Exemed Pharmaceuticals / M/s Torrent Pharmaceuticals Limited	19.00 (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)
		Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)			
4 (xii) (B) (xvii)	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) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Torrent Pharmaceuticals Limited	20.11 (Note 2)
4 (xii) (B) (xviii)	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	Each uncoated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Alembic Pharmaceuticals Limited	19.11 (Note 2)
4 (xii) (C) (i)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	Each uncoated bilayered tablet contains: Sitagliptin Phosphate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 500mg (Sustained Release Form)	1 Tablet	M/s Alkem Health Science (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Ltd	16.33 (Note 2)
4 (xii) (C) (ii)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	Each uncoated bilayered tablet contains: Sitagliptin Phosphate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 1000mg (Sustained Release Form)	1 Tablet	M/s Alkem Health Science (A Unit of Alkem Laboratories Ltd.) / M/s Alkem Laboratories Ltd	17.69 (Note 2)
4 (xii) (D) (i)	Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP (As Sustained Release) 100mg Metformin Hydrochloride IP (As Sustained Release) 500mg	1 Tablet	M/s Synkem Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	12.11 (Note 2)
4 (xii) (D) (ii)	Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP (As Sustained Release) 100mg Metformin Hydrochloride IP (As Sustained Release) 500mg	1 Tablet	M/s Synkem Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	12.11 (Note 2)
4 (xii) (D) (iii)	Vildagliptin (SR) and Metformin Hydrochloride	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As	1 Tablet	M/s Synkem Pharmaceuticals Ltd. / M/s Zydus	12.28 (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)
	(SR) Tablets	Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)		Healthcare Limited	
4 (xii) (D) (iv)	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Lupin Limited	12.28 (Note 2)
4 (xii) (D) (v)	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Eris Lifesciences Limited	12.28 (Note 2)
4 (xii) (D) (vi)	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Limited	12.28 (Note 2)
4 (xii) (D) (vii)	Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP (As Sustained Release) 100mg Metformin Hydrochloride IP (As Sustained Release) 1000mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	13.65 (Note 2)
4 (xii) (D) (viii)	Vildagliptin (SR) & Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP (As Sustained Release) 100mg Metformin Hydrochloride IP (As Sustained Release) 1000mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	13.65 (Note 2)
4 (xii) (D) (ix)	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Lupin Limited	13.82 (Note 2)
4 (xii) (D) (x)	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Zydus Healthcare Limited	13.82 (Note 2)
4 (xii) (D) (xi)	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Eris Lifesciences Limited	13.82 (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)
4 (xii) (D) (xii)	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Limited	13.82 (Note 2)
4 (xii) (D) (xiii)	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 500mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	12.14 (Note 2)
4 (xii) (D) (xiv)	Vildagliptin (SR) and Metformin Hydrochloride (SR) Tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100mg (As Sustained Release) Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	13.68 (Note 2)
4 (xiii)	Zinc Sulfate Monohydrate, Sodium Citrate, Potassium Chloride, Sodium Chloride, Dextrose Anhydrous Sachet	Each 4.4g sachet contains: Zinc Sulfate Monohydrate IP 0.011g Sodium Citrate IP 0.58g Potassium Chloride IP 0.30g Sodium Chloride IP 0.52g Dextrose Anhydrous IP 2.70g	Per Sachet of 4.4 gm	M/s Acme Diet Care Pvt. Ltd. / M/s RPG Life Sciences Ltd.	6.12

Note 1: The Authority decided to defer the Agenda item in view of certain points raised during the discussion and directed that the matter may be re-examined.

Note 2: The Authority deliberated on the retail prices recommended by the Multidisciplinary Committee of Experts (MDC) w.r.t. the new drug(s) that contain molecules or components or ingredients, that have become off-patent or about to become off-patent (**Agenda Item 4(xii)**), in light with the DPCO amendment vide S.O. 2165(E) dated 11.05.2023. The Authority also noted the representations (representation of M/s Zydus Healthcare Limited dated 1.06.2023 and M/s Emcure Pharmaceuticals Limited dated 8.06.2023) received in respect of the methodology adopted by the MDC while recommending the prices of such formulations in its 51st meeting within 10 working days of uploading of minutes of 51st MDC on NPPA's website. After detailed deliberations, it was noted by the Authority that the methodology followed by MDC is in line with the DPCO amendment vide S.O. 2165(E) dated 11.05.2023 and hence, decided to reject the representations and approved the retail prices recommended by the MDC.

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

5.1 Noted.

6. Agenda item no. 6 – Minutes of 51st meeting of Multidisciplinary Committee of Experts held on 24.05.2023.

Noted.

7. Agenda item no. 7 -Fixation of ceiling prices of 02 scheduled formulation under Revised Schedule-I (NLEM, 2022).

7.1 The Authority noted that prices of 689 formulations have been notified under revised Schedule-I, DPCO, 2013 (NLEM, 2022) based on the methodology deliberated in the 104th, 111th and 112th meetings of the Authority held on 23.11.2022, 29.03.2023 and 01.05.2023 respectively for fixation of ceiling price of scheduled formulations.

7.2 The Authority noted that ceiling prices for 2 scheduled formulations i.e. Dabigatran capsule 110 mg and 150 mg were deferred in the previous Authority meeting with a direction to re-examine the representations received.

7.3 The Authority was apprised that the representations received for the said two formulations are related to Price to Retailer (PTR) revision based on Wholesale Price Index (WPI) increase availed by the companies in April, 2022 but not being reflected in the July, 2022 Pharmatrac database. The Authority noted that the revision in PTR has been made based on verification done with the Form-V submitted by the companies till 31.07.2022 i.e., the month and the database used for fixation of ceiling prices since these are newly added scheduled formulations and Form II is not applicable in these cases. Accordingly, the Authority approved the ceiling prices for the two scheduled formulations under Para 4(1) of DPCO 2013 as below:

Table 2: Ceiling Price fixation under Para 4 (1)of DPCO, 2013

S.No	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./ Unit)	SO& dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1.	10.5.3	Dabigatran	Capsule 110mg	Newly Added	Newly Added	31.81	1 Capsule
2.	10.5.3	Dabigatran	Capsule 150mg	Newly Added	Newly Added	35.59	1 Capsule

8. Agenda item no. 8 - Extension of validity of TMR notification pertaining to Oxygen Concentrators.

8.1 The Authority deliberated upon the matter and directed that the MRPs of Oxygen Concentrators shall continue to be monitored as per Para 20(1) of DPCO, 2013.


9. Agenda item no. 9 - Extension of validity of TMR notification pertaining to five medical devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer & (v) Glucometer.

9.1 The Authority deliberated upon the matter and directed that the MRPs of five medical devices, namely, (1) Pulse Oximeter (2) Blood Pressure Monitoring Machine, (3) Nebulizer, (4) Digital Thermometer, and (5) Glucometer shall continue to be monitored as per Para 20(1) of DPCO,2013.

10. Agenda item no. 10 -Report of the Committee to examine the issue relating to 20% reduction of one of the components having lower price while calculating the price of FDCs by the Multidisciplinary Committee of Experts.

10.1 The Authority deliberated upon the matter and decided that the report of the committee may be placed in the meeting of Multidisciplinary Committee of Experts (MDC) for their comments/observations (if any) since MDC is primarily implementing the said principles while recommending the prices of new drugs.

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


(Dr. Vinod Kotwal)
Member Secretary