

**Minutes of the 248<sup>th</sup> (overall) and 116<sup>th</sup> meeting of the Authority under DPCO, 2013 held on 06.09.2023 at 11:00 AM.**

The 248<sup>th</sup> meeting of the Authority (overall), which is the 116<sup>th</sup> meeting under the DPCO, 2013, was held on 6<sup>th</sup> September, 2023 at 11:00 AM 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
- (ii) Shri Mahaveer Saini, Deputy Director (Pricing)
- (iii) Shri Rajesh Kumar T, Deputy Director (Medical Device and Legal)
- (iv) Ms. Yuvika Panwar, Assistant Director (Pricing)

**II. Agenda items**

**1. Agenda item no. 1 - Confirmation of Minutes of the 115<sup>th</sup> Meeting held on 31.07.2023.**

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 115<sup>th</sup> Meeting held on 31.07.2023.**

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 (xxxv) (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 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.**

Table No. 1: Retail price fixation of new drugs

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (i)	Rosuvastatin & Clopidogrel Capsules	<b>Each hard gelatin capsule contains:</b> Rosuvastatin Calcium IP eq. to Rosuvastatin 20mg (as Pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd / M/s Torrent Pharmaceuticals Limited	18.95
4 (ii)	Diclofenac Diethylamine, Methyl Salicylate and Menthol Gel	<b>Composition:</b> Diclofenac Diethylamine IP 2.32 % w/w eq. to Diclofenac Sodium IP 2.0 % w/w Methyl Salicylate IP 10 % w/w Menthol IP 5 % w/w	1 Gram	M/s Daiwik Pharmasphere Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	4.08
4 (iii)	Linagliptin and Metformin Hydrochloride Tablets	<b>Each film coated tablet contains:</b> Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Abbott Healthcare Pvt. Ltd.	8.97
4 (iv)	Linagliptin + Metformin Hydrochloride Tablet	<b>Each film coated tablet contains:</b> Linagliptin 2.5mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Sai Primus Life Biotech Private Limited / M/s Primus Remedies Pvt. Ltd.	12.18
4 (v)	Linagliptin + Metformin Hydrochloride Tablet	<b>Each film coated tablet contains:</b> Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	9.60
4 (vi)	Linagliptin + Metformin Hydrochloride Tablet	<b>Each film coated tablet contains:</b> Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	8.97
4 (vii)	Linagliptin + Metformin Hydrochloride Tablet	<b>Each film coated tablet contains:</b> Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	8.97
4 (viii)	Linagliptin + Metformin Hydrochloride Tablet	<b>Each film coated tablet contains:</b> Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd.	9.60
4 (ix)	Linagliptin and Metformin Hydrochloride	<b>Each film coated tablet contains:</b> Linagliptin 2.5mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Abbott	9.60

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Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablets	Metformin Hydrochloride IP 1000mg		Healthcare Pvt. Ltd.	
4 (x)	Pantoprazole Sodium (EC) & Levosulpiride (SR) Capsules	<b>Each Hard gelatine capsule contains:</b> Pantoprazole Sodium Sesquihydrate IP eq. to Pantoprazole 40mg (As Enteric Coated Pellets) Levosulpiride 75mg (As Sustained Release Pellets)	1 Capsule	M/s Lucent Biotech Limited / M/s Torrent Pharmaceuticals Ltd.	15.96
4 (xi)	Budesonide and Formoterol Fumarate	<b>Each 2 ml respule contains:</b> Budesonide IP 1mg Formoterol Fumarate Dihydrate eq. to Formoterol Fumarate 20 mcg	Per 2 ml Mistpules	M/s Axa Parenterals Ltd./ M/s J.B. Chemicals & Pharmaceuticals Ltd.	56.20
4 (xii)	Itraconazole Capsules (Supra-Bioavailable Formulation)	<b>Each Hard gelatine capsule contains:</b> (Supra-Bioavailable formulation) Itraconazole IP 130mg	1 Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Dr. Reddy's Laboratories Limited	19.30
4 (xiii)	Linagliptin + Metformin Hydrochloride Extended Release Tablet	<b>Each film coated bilayer tablet contains:</b> Linagliptin 2.5mg Metformin Hydrochloride (As extended release)IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	9.60
4 (xiv)	Linagliptin + Metformin Hydrochloride Tablet	<b>Each film coated tablet contains:</b> Linagliptin 2.5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	8.97
4 (xv)	Linagliptin + Metformin Hydrochloride Tablet	<b>Each film coated tablet contains:</b> Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	9.60
4 (xvi)	Linagliptin + Metformin Hydrochloride (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Linagliptin 2.5mg Metformin Hydrochloride IP 1000mg (as Extended release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Ltd.	9.60
4 (xvii)	Itraconazole Capsules 65mg (Supra-Bioavailable Formulation)	<b>Each Hard gelatine capsule contains:</b> (Supra-Bioavailable formulation) Itraconazole IP 65mg	1 Capsule	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Dr. Reddy's Laboratories	10.81

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
				Limited	
4 (xviii)	Diclofenac Potassium & Metaxalone Tablets	<b>Each uncoated tablet contains:</b> Diclofenac Potassium IP 50mg Metaxalone USP 400mg	1 Tablet	M/s Windlas Biotech Limited / M/s Intas Pharmaceuticals Ltd.	15.08
4 (xix)	Cefuroxime Axetil & Potassium Clavulanate Tablets	<b>Each film coated tablet contains:</b> Cefuroxime Axetil IP eq. to Cefuroxime 500mg Potassium Clavulanate Diluted IP Eq. to Clavulanic Acid 125mg	1 Tablet	M/s Hetero Labs Limited / M/s Sun Pharmaceuticals Industries Limited	55.23
4 (xx)	Levosalbutamol and Ipratropium Bromide respule solution	<b>Each 2.5ml contains:</b> Levosalbutamol Sulphate IP eq. to Levosalbutamol 1.25mg Ipratropium Bromide IP eq. to Ipratropium (anhydrous) 500mcg	1 ML	M/s AXA Parenterals Ltd. / M/s Mankind Pharma Ltd.	5.49
4 (xxi)	Moxifloxacin Eye Drops	<b>Composition:</b> Moxifloxacin hydrochloride IP eq. to Moxifloxacin 0.5%w/v	1 ML	M/s East African (India) Overseas / M/s Torrent Pharmaceuticals Limited	17.00
4 (xxii)	Pantoprazole Dual Release Gastro Resistant Tablets	<b>Each Dual Release Gastro Resistant Tablet Contains:</b> Pantoprazole Sodium IP eq. to Pantoprazole 80mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	15.30
4 (xxiii)	Telmisartan, Chlorthalidone & Cilnidipine tablets	<b>Each film coated tablet contains:</b> Telmisartan IP 40mg Chlorthalidone IP 6.25mg Cilnidipine IP 10mg	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	13.05
4 (xxiv)	Povidone Iodine Gargle	<b>Composition:</b> Povidone Iodine IP 0.5% w/v (available Iodine 0.05% w/v)	1 ml	M/s Pontika Aerotech Limited / M/s Emcure Pharmaceuticals Limited	0.70
4(xxv)	Paracetamol and Dicyclomine Hydrochloride Tablets	<b>Each uncoated tablet contains:</b> Paracetamol IP 325mg Dicyclomine Hydrochloride IP 20mg	1 Tablet	M/s Prosperity Drugs Pvt. Ltd. / M/s Torrent Pharmaceuticals Limited	Deferred (Note 1)
4 (xxvi) a	Teneligliptin, Pioglitazone and Metformin Hydrochloride (as Sustained Release)	<b>Each Film coated bilayered tablet contains:</b> Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Micro Labs Limited	16.07

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablets	Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg Metformin Hydrochloride IP 500mg (as Sustained Release)			
4 (xxvi) b	Teneligliptin, Pioglitazone and Metformin Hydrochloride (as Sustained Release) Tablets	<b>Each Film coated bilayered tablet contains:</b> Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg Metformin Hydrochloride IP 1000mg (as Sustained Release)	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Micro Labs Limited	17.85
4 (xxvii) a	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	<b>Each film coated Bilayered Tablet Contain:</b> 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 Mascot Health Series Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	16.06
4 (xxvii) b	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	<b>Each film coated Bilayered Tablet Contain:</b> 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 Mascot Health Series Pvt. Ltd. / M/s Eris Lifesciences Limited	16.06
4 (xxvii) c	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	<b>Each film coated Bilayered Tablet Contain:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Intas Pharmaceuticals Ltd.	16.06

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		IP 500mg (Sustained Release Form)			
4 (xxvii) d	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	<b>Each film coated Bilayered Tablet</b> <b>Contain:</b> 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 Emcure Pharmaceuticals Ltd.	16.09
4 (xxvii) e	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	<b>Each film coated Bilayered Tablet</b> <b>Contain:</b> 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 La Renon Healthcare Private Limited	16.09
4 (xxvii) f	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	<b>Each film coated Bilayered Tablet</b> <b>Contain:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 1000mg (Sustained Release Form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	17.13
4 (xxvii) g	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	<b>Each film coated Bilayered Tablet</b> <b>Contain:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 1000mg (Sustained Release Form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Eris Lifesciences Limited	17.13
4 (xxvii) h	Sitagliptin, Pioglitazone	<b>Each film coated Bilayered Tablet</b>	1 Tablet	M/s Akums Drugs & Pharmaceuticals	17.13

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	and Metformin Hydrochloride (Sustained Released) Tablet	<b>Contain:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 1000mg (Sustained Release Form)		Ltd. / M/s Intas Pharmaceuticals Ltd.	
4 (xxvii) i	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	<b>Each film coated Bilayered Tablet</b> <b>Contain:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 1000mg (Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	17.16
4 (xxvii) j	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablet	<b>Each film coated Bilayered Tablet</b> <b>Contain:</b> Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Pioglitazone Hydrochloride IP eq. to Pioglitazone 15 mg Metformin Hydrochloride IP 1000mg (Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s La Renon Healthcare Private Limited	17.16
4 (xxviii) a	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	<b>Each film coated bilayer tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride IP (as Sustained Release) 500mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	18.00
4 (xxviii) b	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release)	<b>Each uncoated bilayer tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride	1 Tablet	M/s Exemed Pharmaceuticals / M/s Alkem Laboratories Limited	16.29

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Tablets	(as Sustained Release) IP 500mg			
4 (xxviii) c	Dapagliflozin, Vildagliptin (As Sustained release) and Metformin Hydrochloride (as Sustained Release) Tablets	<b>Each film coated bilayer tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride IP (as Sustained Release) 1000mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	19.00
4 (xxix) a	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (ER) Tablets	<b>Each film coated tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg (As Extended Release form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Alkem Laboratories Limited	14.59
4 (xxix) b	Dapagliflozin, Sitagliptin and Metformin Hydrochloride (ER) Tablets	<b>Each film coated tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 50mg Metformin Hydrochloride IP 500mg (As Extended Release form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Alkem Laboratories Limited	13.62
4 (xxx) a	Linagliptin + Metformin Hydrochloride Extended Release Tablet	<b>Each film coated bilayer tablet contains:</b> Linagliptin 5mg Metformin Hydrochloride (As extended release) IP 1000mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Intas Pharmaceuticals Ltd.	14.37
4 (xxx) b	Linagliptin + Metformin Hydrochloride (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Linagliptin 5mg Metformin Hydrochloride IP 1000mg (as Extended release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Cipla Ltd.	14.37
4 (xxx) c	Linagliptin + Metformin Hydrochloride (ER) Tablet	<b>Each film coated tablet contains:</b> Linagliptin 5mg Metformin Hydrochloride IP 1000mg (as Extended	1 Tablet	M/s Exemed Pharmaceuticals Ltd. / M/s Micro Labs Ltd.	14.37



Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		release)			
4 (xxx) d	Linagliptin + Metformin Hydrochloride (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Linagliptin 5mg Metformin Hydrochloride (as Extended release) IP 1000mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Torrent Pharmaceuticals Ltd.	14.00
4 (xxx) e	Linagliptin + Metformin Hydrochloride (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Linagliptin 5mg Metformin Hydrochloride (as Extended release) IP 1000mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Lupin Limited	14.37
4 (xxxii)	Metoprolol Succinate Extended Release, Amlodipine 5mg & Telmisartan Tablet	<b>Each film coated bilayered tablet contains:</b> Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (As Extended release) Amlodipine Besilate IP IP eq. to Amlodipine 5mg Telmisartan IP 40mg	1 Tablet	M/s Ajanta Pharma Limited	14.23
4 (xxxiii)	Ambroxol Hydrochloride, Salbutamol Sulphate, Guaiphenesin & Methol Liquid	<b>Each 5ml contains:</b> Ambroxol Hydrochloride IP 15mg Salbutamol Sulphate IP eq. to Salbutamol 1mg Guaiphenesin IP 50mg Methol IP 1mg	1 ml	M/s Naxpar Pharma Pvt. Ltd. / M/s Geno Pharmaceuticals Pvt. Ltd.	0.52
4 (xxxiiii)	Lobeglitazone Sulfate & Glimepiride tablet	<b>Each uncoated Bilayer tablet contains:</b> Lobeglitazone Sulfate 0.5mg Glimepiride IP 1mg	1 Tablet	M/s Glenmark Pharmaceuticals Limited	11.39
4 (xxxv)	Combikit of Clarithromycin Tablets IP, Esomeprazole Tablets IP & Amoxicillin Tablets USP	<b>Each Strip contains:</b> A. Clarithromycin Tablets IP 2 Tablets Each film coated tablet contains: Clarithromycin IP 500mg B. Esomeprazole Tablets IP 2 Tablets Each Enteric coated tablet contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg C. Amoxicillin Tablets USP 2 Tablets	Each Strip	M/s Malik Lifesciences Pvt. Ltd. / M/s Cipla Limited	151.98

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Each Film coated tablet contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 1000mg			
4 (xxxv)	Brinzolamide, Brimonidine Tartrate & Timolol Ophthalmic suspension	<b>Each ml contains:</b> Brinzolamide IP 10mg Brimonidine Tartrate IP 2 mg Timolol Maleate eq. to Timolol IP 5 mg Benzalkonium Chloride Solution IP 0.2mg (As Preservative)	1 ml	M/s Micro labs Limited	105.25

**Note 1:** One of the authority member observed that 7 companies have been considered for the retail price fixation. However, as per web-sources there are other companies also marketing this formulation. The Authority deliberated on the matter in detail and decided that the agenda item may be deferred and confirmation may be obtained from M/s Pharmatrac.

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

5.1 Noted.

**6. Agenda item no. 6 -Minutes of 53<sup>rd</sup> meeting of Multidisciplinary Committee of Experts held on 08.08.2023.**

Noted.

**7. Agenda item no. 7 -Application for "Special Feature rate" for scheduled products (i) Tazofic Injection 2.25 gm containing Piperacillin 2gm+Tazobactam 250mg and (ii) Tazofic Injection 4.5 gm containing Piperacillin 4gm+Tazobactam 500 mg under Para 11(3) of DPCO 2013.**

7.1 The Authority noted that the matter was earlier discussed in 102<sup>nd</sup> and 113<sup>th</sup> meeting of Authority held on 27.09.2022 and 26.05.2023 respectively. The Authority deliberated on the matter in detail and decided to allow additional 15% price over the present applicable ceiling price of the formulation for incremental innovation for packaging based on the recommendation of 52<sup>nd</sup> meeting of MDC held on 11.07.2023. Accordingly, the following ceiling prices are approved for M/s Gufic Biosciences Limited under para 11(3) of DPCO 2013-

Sl. No.	Medicine Dosage form and strength	Ceiling price under Para 11(3) of DPCO 2013
(a)	(b)	(c)
1	Powder for Injection Piperacillin (2g) + Tazobactam (250mg)	Rs. 220.26 per Dual chamber bag
2	Powder for Injection Piperacillin (4g) + Tazobactam (500mg)	Rs. 459.28 per Dual chamber bag

**8. Agenda item no. 8 -Ceiling Prices of Orthopedic Knee Implants for Knee Replacement System.**

8.1 The Authority noted that the knee implants ceiling prices were notified vide notification S.O. 4343(E) dated 15th September 2022 which is in force up to 15th September 2023. The authority deliberated upon the matter in detail and examined the requests made by various industry associations and companies highlighting various factors such as fluctuations in foreign exchange; increase in manpower costs, freight cost, WPI; supply chain problems, etc.

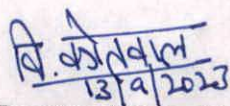
8.2 The Authority observed that the annual WPI w.e.f. 01.04.2020, 01.04.2021, 01.04.2022 and 01.04.2023 was 1.88468%, 0.53638%, 10.76607%, and 12.1218% respectively. The Authority observed that the non-scheduled medical devices/drugs are monitored under para 20(1) of DPCO,2013 and the Knee Implants are non-scheduled devices/drugs.

8.3 After taking all the above into consideration, the Authority decided that in continuation to the notifications S.O. 2668(E) dated 16th August 2017, S.O. 3987(E) dated 13th August 2018, S.O. 2934(E) dated 13th August 2019, S.O. 2768(E) dated 14th August 2020, S.O. 3147 (E) dated 15th September 2020, S.O. 3670(E) dated 10th Sept 2021 and S.O. 4343(E) dated 15th September 2022 regarding fixation of ceiling prices of orthopedics knee implants under para 19 of DPCO, 2013, the ceiling price shall continue for one year i.e., 15th Sept 2024 or till further order, whichever is earlier.

8.4 Further, the ceiling prices shall be monitored as per the provisions of paragraph 20(1) of DPCO,2013. The Notes (b) to (t) of the Notification S.O. 2668(E) dated 16th August 2017 shall remain in force during the currency of this order.

8.5 Further, the ceiling price of orthopedics knee implants will be reviewed after a period of one year.

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

  
13/9/2023  
(Dr. Vinod Kotwal)  
Member Secretary