

मिसिलस.- 8(126)/2024/डी.पी/एनपीपीए-डीवी-II

F. No. 8(126)/2024/DP/NPPA-Div. II

कार्यवाहीस. : 258/126/2024/F

Proceeding No: 258/126/2024/F

Minutes of the 258th (overall) and 126th meeting of the Authority under DPCO, 2013 held on 09.09.2024 at 11.00a.m.

The 258th meeting of the Authority (overall), which is the 126th meeting under the DPCO, 2013 was held on 09th September, 2024 at 11.00 a.m. under the Chairmanship of Dr. Arunish Chawla, Chairman, NPPA. The following Authority members were present during the meeting:

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

Shri Ranga Chandrashekar, Joint Drug Controller, CDSCO, Ministry of Health & Family Welfare.

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

- (i) Shri Sanjay Kumar, Advisor (Cost)
- (ii) Ms. RashmiTahiliani, Director (Pricing)
- (iii) Shri R Jegan, Director (Medical Devices)
- (iv) Shri Mahaveer Saini, Deputy Director (Pricing)
- (v) Shri Rajesh Kumar T, Deputy Director (Medical Devices)
- (vi) Ms. Yuvika Panwar, Assistant Director (Pricing)
- (vii) Shri Raushan Kumar, Assistant Director (Medical Devices)

1. Agenda item no. 1 - Confirmation of Minutes of the 125th Meeting held on 25.07.2024.

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 125th Meeting held on 25.07.2024.

2.1 Noted.

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

3.1 Noted.

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

4.1 The Authority deliberated on 65 (Sixty Five) cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (lxv) falling under the purview of Para 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of 62 (Sixty two) new drugs under Para 5 and 15 of the DPCO 2013 as given in **Table 1 below.**

Table No. 1: Retail price fixation of new drugs

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.	4 (i)	Ibuprofen and Paracetamol Suspension	Each 5ml contains: Ibuprofen IP 100 mg + Paracetamol IP 162.5mg	1 ml	M/s Innova Captab Ltd/ M/s Dr. Reddy's Laboratories Ltd	0.50
2.	4 (ii)	Telmisartan, Amlodipine and Hydrochlorothiazide tablets	Each film coated tablet contains: Telmisartan IP 40mg + Amlodipine Besilate IP eq. to Amlodipine 5mg + Hydrochlorothiazide IP 12.5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd/ M/s Sun Pharmaceutical Industries Ltd	10.23
3.	4 (iii)	Telmisartan, Cilnidipine and Chlorthalidone tablets	Each film coated tablet contains: Telmisartan IP 40mg, Cilnidipine IP 10mg & Chlorthalidone IP 12.5mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	14.73
4.	4 (iv)	Telmisartan, Chlorthalidone & Amlodipine tablets	Each film coated tablet contains: Telmisartan IP 40mg Chlorthalidone IP 6.25mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Eris Lifesciences Limited	10.65
5.	4 (v)	Telmisartan, Cilnidipine & Chlorthalidone Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40mg Cilnidipine IP 10mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Windlas Biotech Ltd. / M/s Emcure Pharmaceuticals Limited	14.85

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
6.	4 (vi)	Amlodipine, Telmisartan and Metoprolol Succinate (Extended Release) tablets	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.5 mg eq. to Metoprolol Tartrate 50mg (as extended release form) Telmisartan IP 40mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Cipla Limited	13.20
7.	4 (vii)	Amlodipine, Telmisartan and Metoprolol Succinate (Extended Release) tablets	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.5 mg eq. to Metoprolol Tartrate 50mg (as extended release form) Telmisartan IP 40mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Akumentis Healthcare Ltd.	13.20
8.	4 (viii)	Metoprolol Succinate (ER), Cilnidipine & Telmisartan tablets	Each film coated bilayered tablet contains: Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (As Extended release from) Cilnidipine IP 10mg Telmisartan IP 40mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s USV Private Limited	9.82
9.	4 (ix)	Metoprolol Succinate (ER), Cilnidipine & Telmisartan Tablets	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.5mg eq. to Metoprolol Tartrate 50mg (As Extended release from) Cilnidipine IP 10mg Telmisartan IP 40mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s USV Private Limited	12.50
10.	4(x)	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 and Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	11.21

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
11.	4(xi)	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 and Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	9.65
12.	4(xii)	Bisoprolol Fumarate and Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5 mg Telmisartan IP 40 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Cipla Limited	9.65
13.	4(xiii)	Bisoprolol Fumarate and Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5 mg Telmisartan IP 40 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Cipla Limited	11.21
14.	4(xiv)	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 Medley Pharmaceuticals Ltd.	9.65
15.	4(xv)	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 Medley Pharmaceuticals Ltd.	11.21
16.	4(xvi)	Levofloxacin Infusion IP	Each 100ml Contains: Levofloxacin Hemihydrate IP eq to Levofloxacin 500mg + Sodium Chloride IP 900 mg	1 ml	M/s Pure and Cure Healthcare Pvt Ltd / M/s Dr Reddy's Laboratories Ltd	1.51
17.	4(xvii)	Moxifloxacin Eye drops IP	Composition: Moxifloxacin Hydrochloride IP eq. to Moxifloxacin 0.5% w/v	1 ml	M/s Appasamy Ocular Devices (P) Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	27.00
18.	4(xviii)	Moxifloxacin & Ketorolac Tromethamine Eye drops IP	Composition: Moxifloxacin Hydrochloride IP eq. to Moxifloxacin 0.5% w/v Ketorolac Tromethamine IP 0.4% w/v Benzalkoniumchloride Solution 0.01%v/v (as preservative)	1 ml	M/s Appasamy Ocular Devices (P) Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	25.32

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
19.	4(xix)	Moxifloxacin & Dexamethasone 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 Appasamy Ocular Devices (P) Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	25.04
20.	4(xx)	Ofloxacin & Dexamethasone Sodium Phosphate Ophthalmic Solution	Composition: Ofloxacin IP 0.3% w/v Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1%w/v Benzalkonium Chloride Solution IP 0.02% w/v (as preservative)	1 ml	M/s Hanuchem Laboratories / M/s Mankind Prime Labs Pvt. Ltd.	5.24
21.	4 (xxi)	Chloramphenicol & Dexamethasone Sodium Phosphate Eye/Ear drops	Composition: Chloramphenicol IP 1%w/v Dexamethasone Sodium Phosphate IP 0.1%w/v Phenyl Mercuric Nitrate IP 0.002%w/v (as preservative)	1 ml	M/s Hanuchem Laboratories / M/s Mankind Prime Labs Pvt. Ltd.	5.88
22.	4 (xxii)	Tobramycin and Dexamethasone Ophthalmic Solution	Composition: Tobramycin Sulfate USP eq. to Tobramycin 0.3%w/v + Dexamethasone Sodium Phosphate IP eq. to Dexamethasone Phosphate 0.1%.w/v+ Benzalkonium Chloride Solution IP 0.02%v/v (as preservative)	1 ml	M/s Hanuchem Laboratories / M/s Mankind Prime Labs Pvt. Ltd.	5.78
23.	4 (xxiii)	Aceclofenac + Paracetamol + Serratiopeptidase Tablets	Each film coated tablet contains: Aceclofenac IP 100mg, Paracetamol IP 325mg Serratiopeptidase IP 15mg (As enteric coated tablet eq. to enzyme activity 30000 units)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Abbott Healthcare Pvt. Ltd.	9.74

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
24.	4 (xxiv)	Mefenamic Acid and Paracetamol Tablets	Each uncoated tablet contains: Mefenamic Acid IP 250mg Paracetamol IP 325mg	1 Tablet	M/s Blue Cross Laboratories Pvt. Ltd.	3.82
25.	4 (xxv)	Paracetamol and Mefenamic Acid suspension	Each 5ml contains: Mefenamic Acid 100mg + Paracetamol IP 250mg	1 ml	M/s Windlas Biotech Limited / M/s Biological E. Limited	0.90
26.	4 (xxvi)	Diclofenac Sodium Injection IP	Each ml contains: Diclofenac Sodium IP 75mg	1 ml	M/s Fast Pharma Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	28.70
27.	4 (xxvii)	Lactulose Enema 20% w/v	Each ml contains: Lactulose Concentrate USP eq. to Lactulose 200mg+ Benzyl Alcohol IP 3mg	1 ml	M/s Merrill Pharma Private Ltd. / M/s Alkem Laboratories Ltd.	1.19
28.	4 (xxviii)	Cefadroxil and Clavulanic Acid Dispersible Tablets	Each uncoated dispersible tablet contains: Cefadroxil Monohydrate IP eq. to Cefadroxil 250mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 62.5mg	1 Tablet	M/s Twenty First Century Pharmaceuticals Pvt. Ltd. / M/s Indoco Remedies Limited	9.30
29.	4 (xxix)	Cefadroxil and Clavulanic Acid Tablets	Each film coated tablet contains: Cefadroxil Monohydrate IP eq. to Cefadroxil 500mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125mg	1 Tablet	M/s Twenty First Century Pharmaceuticals Pvt. Ltd. / M/s Indoco Remedies Limited	17.61
30.	4 (xxx)	Ferrous Ascorbate and Folic Acid Suspension IP	Each 5ml contains: Ferrous Ascorbate IP eq. to Elemental Iron 30mg Folic Acid IP 550mcg	1 ml	M/s Tirupati Medicare Ltd. / M/s Intas Pharmaceuticals Ltd.	0.95

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
31.	4 (xxxi)	Combi pack of Clarithromycin Tablets IP, Esomeprazole Tablets IP & Amoxicillin Tablets USP	Each Strip contains: A. Clarithromycin Tablets IP 2 Tablets Each film coated tablet contains: Clarithromycin IP 500mg B. Esomeprazole Tablets IP 2 Tablets Each Enteric coated tablet contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg C. Amoxicillin Tablets USP 2 Tablets Each Film coated tablet contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 750mg	Combi kit pack	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mankind Pharma Limited	166.74
32.	4 (xxxii)	Etoricoxib and Paracetamol Tablets	Each Film Coated tablet contains: Etoricoxib IP (As Micronized) 60 mg Paracetamol IP 325 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Pharmed Limited	9.15
33.	4 (xxxiii)	Etoricoxib and Paracetamol Tablets	Each film coated Tablet contains: Etoricoxib IP 60mg (As micronized) Paracetamol IP 325mg	1 Tablet	M/s Synokem Lifesciences Pvt. Ltd. / M/s Cipla Ltd.	9.15
34.	4 (xxxiv)	Levosulbutamol & Ipratropium Bromide respirator solution	Each 2.5 ml contains: Levosalbutamol Sulphate eq. to Levosalbutamol 1.25 mg + Ipratropium Bromide eq. to Ipratropium (Anhydrous) 500 mcg	1 ml	M/s AxaParenterals Limited / M/s Workcell Solutions Private Limited	5.75
35.	4 (xxxv)	Povidone Iodine Gargle	Composition: Povidone-Iodine IP 2% w/v (Available Iodine 0.2% w/v) Ethanol 95% IP eq. to Absolute Alcohol 8.38% v/v	1 ml	M/s Pontika Aerotech Limited / M/s Abbott Healthcare Pvt. Ltd.	1.96

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
36.	4 (xxxvi)	Omeprazole & Domperidone Capsules IP	Each hard gelatin capsule contains: Omeprazole IP 20mg (as Enteric coated) Domperidone IP 10mg (As Instant release)	1 Capsule	M/s Hetero Healthcare Ltd.	6.28
37.	4 (xxxvii)	Tolperisone Hydrochloride and Paracetamol Tablets	Each film coated tablet contains: Tolperisone Hydrochloride IP 150mg Paracetamol IP 325mg	1 Tablet	M/s Pure and cure Healthcare Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	13.95
38.	4 (xxxviii)	Escitalopram Tablets	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 15mg	1 Tablet	M/s East African (India) Overseas / M/s Torrent Pharmaceuticals Ltd.	13.00
39.	4 (xxxix)	Escitalopram Oxalate + Clonazepam Tablets	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 5mg Clonazepam IP 0.25mg	1 Tablet	M/s East African (India) Overseas / M/s Torrent Pharmaceuticals Ltd.	7.74
40.	4 (xl)	Escitalopram Oxalate + Clonazepam Tablets	Each film coated tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 20mg Clonazepam IP 0.5mg	1 Tablet	M/s East African (India) Overseas / M/s Torrent Pharmaceuticals Ltd.	19.67
41.	4 (xli)	Atorvastatin and Aspirin Capsules	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg, Aspirin IP 150mg (As two enteric coated tablet USP 75mg)	1 Capsule	M/s Unison Pharmaceuticals Pvt. Ltd	2.54
42.	4 (xlii)	Riboflavin, Folic Acid Niacinamide & Lactic Acid Bacillus Tablets	Each uncoated tablet contains: Riboflavin IP 10mg Folic Acid IP 1.5mg Niacinamide IP 100mg Lactic Acid Bacillus 60Million Spores	1 Tablet	M/s Prosperity Drugs Pvt. Ltd. / M/s Intas Pharmaceuticals Ltd.	4.11

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
43.	4 (xliii)	Empagliflozin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Mankind Pharma Limited	15.84
44.	4 (xliv)	Empagliflozin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Mankind Pharma Limited	19.01
45.	4 (xlv)	Empagliflozin and Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500mg	1 Tablet	M/s Mankind Pharma Limited	18.10
46.	4 (xlvi)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablets	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 1000mg (as Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	15.32
47.	4 (xlvii)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablets	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 (as Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Sun Pharma Laboratories Limited	14.00



S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
48.	4 (xlviii)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablets	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 1000mg (as Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Sun Pharma Laboratories Limited	15.32
49.	4 (xlix)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablets	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 (as Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Micro Labs Limited	14.00
50.	4 (l)	Sitagliptin, Pioglitazone and Metformin Hydrochloride (Sustained Released) Tablets	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 1000mg (as Sustained Release Form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Micro Labs Limited	15.32
51.	4 (li)	Sitagliptin, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Apex Laboratories Private Limited	11.60

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
52.	4 (lii)	Sitagliptin, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Apex Laboratories Private Limited	11.60
53.	4 (liii)	Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets	Each film coated bilayer Tablet contains: Linagliptin 5mg Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (as sustained release form)	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	20.33
54.	4 (liv)	Linagliptin, Dapagliflozin & Metformin Hydrochloride (SR) Tablets	Each film coated bilayer Tablet contains: Linagliptin 5mg Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (as sustained release form)	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Ltd.	18.92
55.	4 (lv)	Dapagliflozin, Vildagliptin (SR) and Metformin Hydrochloride (SR) tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg + Vildagliptin IP 100mg (as sustained release) + Metformin Hydrochloride IP 1000mg (as sustained release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	11.70
56.	4 (lvi)	Iron tonic with Vitamin B12 and Folic Acid syrup	Each 5ml contains: Ferric Ammonium Citrate IP 80mg Folic Acid IP 0.166mg Vitamin B12 IP 1mcg	1 ml	M/s Aagya Biotech Private Limited / M/s J. B. Chemicals & Pharmaceuticals Ltd.	[Note 1]

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
57.	4 (lvii)	Empagliflozin + Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Mankind Pharma Limited	11.51
58.	4 (lviii)	Empagliflozin+ Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5mg Metformin Hydrochloride IP 1000mg	1 Tablet	M/s Mankind Pharma Limited	11.38
59.	4 (lix)	Empagliflozin+ Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5mg Metformin Hydrochloride IP 850mg	1 Tablet	M/s Mankind Pharma Limited	17.24
60.	4 (lx)	Calcium carbonate + Magnesium Hydroxide + Zinc Sulphate + Vitamin D3 tablets	Each film coated tablet contains: Magnesium Hydroxide IP eq. to Elemental Magnesium 50mg Vitamin D3 IP 1000IU Zinc Sulphate Monohydrate IP eq. to Elemental Zinc 10mg Calcium Carbonate IP eq. to Elemental Calcium 500mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	10.00
61.	4 (lxi)	Dapagliflozin and Metoprolol tablets	Each film coated bilayered Tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metoprolol Succinate IP 47.5mg eq. to Metoprolol Tartrate 50mg (as Sustained release)	1 Tablet	M/s ERIS Lifesciences Limited	16.77
62.	4 (lxii)	Montelukast and Bilastine tablets	Each film coated tablet contains: Montelukast Sodium IP Eq. to Montelukast 10mg Bilastine IP 40mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Sun Pharma Laboratories Limited	28.76

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
63.	4 (lxiii)	Montelukast and Bilastine tablets	Each film coated tablet contains: Montelukast Sodium IP Eq. to Montelukast 10mg Bilastine IP 40mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Sun Pharmaceutical Industries Limited	28.76
64.	4 (lxiv)	Potassium Chloride Dextrose and Sodium Chloride Injection IP	Each 100ml contains: Potassium Chloride IP 150mg Dextrose Monohydrate IP 5000mg Sodium Chloride IP 900mg	500 ml pack	M/s Otsuka Pharmaceutical India Pvt. Ltd.	(Note 2)
65.	4 (lxv)	Potassium Chloride, Dextrose and Sodium Chloride Injection IP	Each 100ml contains: Potassium Chloride IP 150mg+ Dextrose Monohydrate IP 5000mg Sodium Chloride IP 450mg	500 ml pack	M/s Otsuka Pharmaceutical India Pvt. Ltd.	(Note 2)

Note 1: The Authority observed that M/s J.B. Chemicals & Pharmaceuticals Limited has represented on 12.07.2024 against the draft working sheet uploaded on website on 08.07.2024. In this regard, the Authority directed that the retail price fixation of the formulation may be further re-examined.

Note 2: The Authority noted that M/s Otsuka Pharmaceuticals India Pvt. Ltd represented against the price recommended by MDC in its meeting held on 27.08.2024 stating that their product is large volume parental and that their request should be considered under Para 11(3) in addition to Para 5 and 15. The company has represented that they manufacture the product using technology that ensures stability and safety and is distinguished from standard formulations, in line with non-glass container in plastic bottle with euro head having special features.

The Authority noted that the applications for both the formulations have been filed in Form I without any mention of seeking special price under Para 11 (3), DPCO, 2013. Hence, the application was treated as normal retail price application by MDC. The Authority deliberated upon the matter in detail and mentioned that the company may be asked to resubmit the application under Para 11 (3).

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

5.1 Noted.

6. Agenda item no. 6: Minutes of 61stmeeting of Multidisciplinary Committee of Experts held on 14.08.2024.

6.1 Noted

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

7.1 The Authority noted that DoP issued Review order No. 31015/30/2023-Pricing dated 28.05.2024 in relation to fixation of ceiling price of Chloroquine Phosphate 150 mg tablet at Rs.1.04 per tablet vide S.O. No. 194(E) dated 11.01.2023 directing NPPA to fix the ceiling price as per the extant provisions of DPCO 2013.

7.2 It was noted that M/s IPCA Laboratories Limited filed the review petition with DoP stating that the PTR of Resochin tablets marketed by M/s Bayer Zydus Pharma as considered at Rs 6.46 per 10 tablet is old and hence, incorrect. The correct PTR is Rs. 9.99 for pack of 10

7.3 The Authority noted that M/s Bayer Zydus Pharma had not filed the Form-II for the year 2022-23; hence, the revision in PTR was not carried out. The Authority noted that M/s Bayer Zydus Pharma had applied for discontinuation of Resochin in August, 2019. The company was granted discontinuation permission by NPPA vide letter dated 23.3.2020. Also, the last Form-II filed by M/s Bayer Zydus Pharma was on 20.04.2021. Clarification was sought from M/s Bayer Zydus Pharma wherein the company informed that the last batch was produced in October, 2021 having expiry in September, 2024 and the PTR as per Form-II and Form-V submitted on 20.04.2021 and 26.08.2021 respectively is Rs. 9.99 for 10 tablets. Due to COVID-19 pandemic in March 2020, it continued the manufacturing to support public health without notifying authorities

7.4 The Authority also noted that in case of M/s IPCA Laboratories Limited, there was a typographical error in PTR in worksheet. PTR as appearing in Form II was wrongly considered at Rs.13.83 instead of Rs.10.54.

7.5 The Authority noted that the revised draft working sheet with ceiling price of Rs. 1.33 per tablet was uploaded on website on 31.07.2024 after giving effect of WPI increase of 12.1218% w.e.f. 1.04.2023 and WPI increase of (+)0.00551% w.e.f. 01.04.2024 and no representations were received on it. Accordingly, the Authority approved the revised ceiling price with WPI effect at Rs 1.33 per tablet.

8. Agenda item no. 8: Examination and recommendations of applications received from the company's claiming exemption under Para 32 of DPCO, 2013.

8.1 The Authority noted that presently MDC seeks comments from Patent office in relation to the applications seeking exemption from the provisions of DPCO, 2013 under Para 32 of DPCO, 2013.

8.2 DPIIT vide their letter No. P-24013/3/2023-IPR-III dated 15.02.2024 requested that rather than seeking comments from Patent Office, NPPA may establish a

mechanism to decide on exemption claims under Para 32 of DPCO, 2013 to which a patent officer with expertise in the relevant subject matter may be nominated from O/o CGPDTM, DPIIT.

8.3 The Authority noted that as per the order of DoP No. 31015/14/2017-Pricing dated 30.11.2017, MDC is empowered to invite or co-opt any other specialist depending on exigencies of the circumstances requiring resolution of any specific matter arising out of implementation of various provisions of DPCO, 2013 as and when it may be required. Accordingly, the Committee after detailed deliberations on the subject agreed to invite an officer not below the rank of Deputy Controller of Patents & Designs from the O/o CGPDTM, DPIIT, who is well versed with the subject matter for deliberation on applications seeking exemption under Para 32 of DPCO, 2013. It was also decided that agenda for the deliberations on the applications received under Para 32 of DPCO, 2013 may be sent in advance to O/o CGPDTM, DPIIT

8.4 The Authority deliberated on the matter and accepted the recommendations of the MDC to co-opt a member from the O/o CGPDTM, DPIIT for deliberations on application(s) seeking exemption under Para 32 of DPCO, 2013 including sending the agenda on the said subject to O/o CGPDTM, DPIIT.

9. Agenda item no. 9: Ceiling Prices of Orthopaedic Knee Implants for Knee Replacement System.

9.1 The Authority noted that the knee implants ceiling prices were last notified vide notification S.O. 4078(E) dated 15th September 2023 and it is in force up to 15th September 2024.

9.2 The Authority deliberated in detail on the requests made by various industry associations highlighting the factors such as fluctuations in foreign exchange; increase in manpower costs, freight cost, and supply chain issues.

9.3 The Authority deliberated upon the matter and observed that exchange rate of USD to INR was more or less at the same level during the period under consideration. Also, the sales data submitted by the manufacturers/importers of orthopaedic knee implants companies to NPPA shows an increase of 22.71% over previous period indicating that the existing ceiling prices have contributed to increased access to affordable healthcare to general public.

9.4 Accordingly, the Authority decided that the ceiling prices of knee implant systems as applicable on 15th September 2024 may be further extended for one year up to 15th September 2025.

9.5 The Authority further noted that considering the allowable increase in 2019, 2022 and 2023 as per the provisions of paragraph 20(1) of DPCO, 2013 over the ceiling prices

as notified vide notification dated 16.08.2017, the worked-out ceiling prices to be continued w.e.f. 16.09.2024, are as under:

TABLE 2: Ceiling Prices of Orthopaedic knee Implant system

S. No.	Orthopaedic knee Implant system	Component	Feature/Material of the knee implant	Units (in Nos.)	Ceiling Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
PRIMARY KNEE REPLACEMENT SYSTEM					
1.	Primary knee replacement system	Femoral component by whatsoever name/specification	Titanium alloy (all variants) coated	1	51,562.94
2.	Primary knee replacement system	Femoral component by whatsoever name/specification	Oxidized zirconium (OxZr) alloy (all variants)	1	51,562.94
3.	Primary knee replacement system	Femoral component by whatsoever name/specification	Hi-flex	1	34,419.66
4.	Primary Knee replacement system	Femoral component by whatsoever name/specification	Cobalt chromium (CoCr) alloy (all variants) & other than at serial no 1,2 and 3	1	32,063.79
5.	Primary knee replacement system	Tibial component or Tibial tray by whatsoever name/specification	Titanium alloy (& it's all variants) coated	1	32,316.68
6.	Primary knee replacement system	Tibial component or Tibial tray by whatsoever name/specification	Oxidized zirconium (OxZr) alloy	1	32,316.68
7.	Primary knee replacement system	Tibial component or Tibial tray by whatsoever name/specification	Cobalt chromium (CoCr) alloy & other than at Serial no 5 and 6	1	22,613.69
8.	Primary knee replacement system	Articulating surface or Insert by whatsoever name/specification	Any Material	1	12,711.05
9.	Primary knee replacement system	Patella by whatsoever name/specification	Any Material	1	5,443.79
10.	Primary knee replacement system	Component having Tibial tray and Insert combined as single unit by whatsoever name/specification	Polyethylene or cross-linked polyethylene or highly cross-linked polyethylene or any other material	1	17,249.76

S. No.	Orthopaedic knee Implant system	Component	Feature/Material of the knee implant	Units (in Nos.)	Ceiling Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
11.	Primary knee replacement system	Components having Tibial Tray and Insert combined as single unit by whatsoever name called	Tibial: Metallic Insert: Polyethylene or Polyethylene or cross- linked polyethylene or highly cross-linked Polyethylene or any other material	1	35,332.73
SECONDARY KNEE REPLACEMENT SYSTEM					
12.	Revision Knee Replacement system	Femoral Component by whatsoever name/specification	Any material	1	83,546.87
13.	Revision Knee Replacement system	Tibial component or Tibial Tray by whatsoever name/specification	Any material	1	41,553.82
14.	Revision Knee Replacement system	Articulating surface or Insert by whatsoever name/specification	Any material	1	21,122.97
15.	Revision Knee Replacement system	Patella by whatsoever name/specification	Any material	1	5,443.79

9.6 The Notes (b) to (t) of the Notification S.O. 2668(E) dated 16th August 2017 shall remain in force till 15th September 2025 or till further order, whichever is earlier.

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

वि. कोटवाल
10/9/2024
(Dr. Vinod Kotwal)
Member Secretary