

**Minutes of the 225<sup>th</sup> (overall) and 93<sup>rd</sup> meeting of the Authority under DPCO, 2013 held on 15.11.2021 at 11:30 AM**

The 225<sup>th</sup> meeting of the Authority (overall), which is the 93<sup>rd</sup> meeting under the DPCO, 2013, was held on 15<sup>th</sup> of November 2021 at 11:30 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 Amardeep Singh Chowdhary, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) Dr. V. G. Somani, Drug Controller General of India through Video Conferencing

Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare was also present during the meeting through Video Conferencing

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

- (i) Shri N I Chowdhury, Adviser (Cost)
- (ii) Shri G. L. Gupta, Director (Monitoring & CAPPM-IEC)
- (iii) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (iv) Shri Prasenjit Das, Deputy Director (Pricing)
- (v) Shri Mahaveer Saini, Deputy Director (Pricing)
- (vi) Shri Rajesh Kumar T, Deputy Director (Medical Device, Legal & I.T)

**II. Agenda items**

**1. Agenda item no. 1 - Confirmation of the Minutes of the 92<sup>nd</sup> Meeting held on 08.09.2021.**

1.1 The Authority confirmed the minutes and the corrigendum dated 12.10.2021 without any change.

**2. Agenda item no. 2 - Action Taken Report on decisions taken by NPPA in its 91<sup>st</sup> Meeting & 92<sup>nd</sup> Meeting held on 29.07.2021 & 08.09.2021.**

2.1 The Authority noted that due action has been taken.

2.2 The Authority further directed that henceforth the action taken report in respect of all the decisions taken in the Authority meeting to be presented.

### 3. Agenda item no. 3 – Status of New Drug application

3.1 It was observed that a total of 82 applications were pending as on 31.10.2021 out of which 68 applications were presented for price approval in the current meeting and 14 applications were pending. The Authority further directed that action must be taken to process the applications as per the timelines.

### 4.1 Agenda item no. 4 – New Drug application Price fixation under Para 5 and Para 15 of DPCO, 2013

4.1.1 The Authority discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4(li) (total 51 Form I applications containing retail price fixation of 51 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 50 (fifty) new drugs under Para 5 and 15 of the DPCO 2013, as detailed below:

#### A. Retail price fixed under Para 5 and 15 of DPCO, 2013

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(i)	Telmisartan + Chlorthalidone Tablet	<b>Each uncoated bilayered tablet contains:</b> Telmisartan IP 80.mg Chlorthalidone IP 6.25mg	1 Tablet	M/s Windlas Biotech Pvt. Ltd. /M/s Mankind Pharma Ltd.	16.27 (Note 2)
4(ii)	Cefixime Tablets	<b>Each film coated tablet contains:</b> Cefixime IP as Trihydrate eq. to Anhydrous Cefixime 100mg	1 Tablet	M/s. Hema Laboratories Pvt. Ltd. / M/s Softdeal Pharmaceuticals Pvt. Ltd.	5.99
4(iii)	Tacrolimus Ointment 0.1% w/w	<b>Each gm of Ointment contains:</b> Tacrolimus IP 1mg	1 gram	M/s Helios Pharmaceuticals / M/s Panacea Biotec Pharma Limited	35.44
4(iv)	Tacrolimus Ointment 0.03% w/w	<b>Each gm of Ointment contains:</b> Tacrolimus IP 0.3mg	1 gram	M/s Helios Pharmaceuticals / M/s Panacea Biotec Pharma Limited	16.41
4(v)	Etoricoxib + Paracetamol Tablet	<b>Each film coated tablet contains:</b>	1 Tablet	M/s Acme Lifetech LLP. /	5.50

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Etoricoxib IP 60 mg Paracetamol IP 325 mg		M/s Troikaa Pharmaceuticals Ltd.	
4(vi)	Telmisartan + Chlorthalidone + Metoprolol (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 12.5mg, Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as Extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Ltd.	10.88
4(vii)	Telmisartan + Chlorthalidone + Metoprolol (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 12.5mg, Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as Extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Micro Labs Ltd.	12.91
4(viii)	Calcium + Cholecalciferol Tablets	<b>Each film-coated tablet contains:</b> Calcium (In the form of Calcium hydroxide and Calcium oxide pretreated with heated algae) 500mg Cholecalciferol IP 2000IU,	1 Tablet	M/s USV Private Limited.	12.64 (Note 2)
4(ix)	Cilnidipine, Telmisartan & Chlorthalidone Tablets	<b>Each Film Coated Tablet contains:</b> Cilnidipine IP 10mg Telmisartan IP 40mg Chlorthalidone IP 6.25mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Dr. Reddy's Laboratories Ltd.	11.61 (Note 2)
4(x)	Paracetamol bilayered Tablet 1000mg	<b>Each uncoated bilayered tablet contains:</b> Paracetamol IP 300mg (as	1 Tablet	M/s. Sterling Lab	2.90

7c.

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Immediate release) Paracetamol IP 700mg (as sustained release)			
4(xi)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 6.25mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s Eris Lifesciences Limited	9.86
4(xii)	Glimepiride + Metformin Hydrochloride (as Prolonged release form) Tablet	<b>Each uncoated bilayered tablet contains:</b> Glimepiride IP 2mg, Metformin Hydrochloride IP 500mg (as Prolonged release form)	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. /M/s J. B. Chemicals & Pharmaceuticals Ltd.	9.41
4(xiii)	Telmisartan, Chlorthalidone & Amlodipine Tablet	<b>Each film coated tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 6.25mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. /M/s Mankind Pharma Ltd.	8.92
4(xiv)	Telmisartan, Chlorthalidone & Amlodipine Tablet	<b>Each film coated tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Amlodipine Besylate IP eq. to Amlodipine 5mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. /M/s Mankind Pharma Ltd.	9.95
4(xv)	Chlorthalidone + Telmisartan Tablet	<b>Each film coated Tablet contains:</b> Chlorthalidone IP 6.25mg Telmisartan 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Micro Labs Limited	8.60 (Note 2)
4(xvi)	Metoprolol Tartrate + Ivabradine Tablet	<b>Each film coated tablet contains:</b> Metoprolol Tartrate	1 Tablet	M/s. Ajanta Pharma Limited	15.46 (Note 3)

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		IP 25mg Ivabradine Hydrochloride eq. to Ivabradine 5mg			
4(xvii)	Metoprolol Tartrate + Ivabradine Tablet	<b>Each film coated tablet contains:</b> Metoprolol Tartrate IP 50mg Ivabradine Hydrochloride eq. to Ivabradine 5mg	1 Tablet	M/s. Ajanta Pharma Limited	17.74 (Note 3)
4(xviii)	Cyclosporine Ophthalmic Solution	<b>Each ml contains:</b> Cyclosporine IP 0.9mg Aqueous Buffered Vehicle q.s.	Per 0.25 ml pack	M/s Sun Pharmaceutical Industries Limited	Deferred (Note 4)
4(xix)	Lignocaine Hydrochloride, Chlorhexidine Gluconate & Metronnidazole Gel	<b>Gel contains:</b> Lignocaine Hydrochloride IP 2.0%w/w, Chlorhexidine Gluconate IP 1% w/w, Metronnidazole 1% IP w/w	1 Gram	M/s Curetech Skincare / M/s J.B.Chemicals & Pharmaceuticals Ltd.	3.48 (Note 2)
4(xx)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s Eris Lifesciences Limited	10.88
4(xxi)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 6.25mg Metoprolol Succinate IP 47.5mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s Eris Lifesciences Limited	10.81
	Telmisartan,	<b>Each film coated</b>	1	M/s Ravenbhel	



S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxii)	Chlorthalidone & Metoprolol (ER) Tablet	<b>bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 47.5mg eq. to Metoprolol Tartrate (as extended release) 50mg	Tablet	Healthcare Pvt. Ltd. /M/s Eris Lifesciences Limited	12.91
4(xxiii)	Azelnidipine + Telmisartan Tablet	<b>Each film coated bi-layered tablet contains:</b> Azelnidipine IP 8mg Telmisartan IP 40mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Ipca Laboratories Limited	11.37
4(xxiv)	Azelnidipine + Telmisartan Tablet	<b>Each film coated bi-layered tablet contains:</b> Azelnidipine IP 8mg Telmisartan IP 80mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Ipca Laboratories Limited	13.27
4(xxv)	Rosuvastatin + Clopidogrel Capsule	<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. / Cadila Pharmaceuticals Ltd.	19.64
4(xxvi)	Rosuvastatin + Aspirin Capsule	<b>Each hard gelatin capsule contains:</b> Rosuvastatin Calcium IP eq. to Rosuvastatin 10mg (As Pellets) Aspirin IP 75mg (As enteric coated Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / Cadila Pharmaceuticals Ltd.	5.99
4(xxvii)	Telmisartan + Amlodipine Tablet	<b>Each Uncoated bilayered Tablet contains:</b> Telmisartan IP 40mg Amlodipine Besilate IP eq. Amlodipine 5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s J.B. Chemicals & Pharmaceuticals Ltd.	9.51
	Telmisartan +	<b>Each film coated</b>	1	M/s Pure and	

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxviii)	Cilnidipine + Metoprolol Succinate (ER) Tablet	<b>tablet contains:</b> Telmisartan IP 40mg Cilnidipine IP 10mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartarate 25 mg (as Extended Release form)	Tablet	Cure Healthcare Pvt. Ltd. / M/s J.B.Chemicals & Pharmaceuticals Ltd.	10.68
4(xxix)	Telmisartan + Cilnidipine + Metoprolol Succinate (ER) Tablet	<b>Each film coated tablet contains:</b> Telmisartan IP 40mg Cilnidipine IP 10mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartarate 50 mg (as Extended Release form)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s J.B.Chemicals & Pharmaceuticals Ltd.	12.95
4(xxx)	Glimepiride + Metformin Hydrochloride (as Prolonged release form) Tablet	<b>Each uncoated bilayered tablet contains:</b> Glimepiride IP 1mg, Metformin Hydrochloride IP 500mg (as Prolonged release form)	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. /M/s J. B. Chemicals & Pharmcaeuticals Ltd.	6.72
4(xxxi)	Atorvastatin + Aspirin Capsule	<b>Each hard Gelatin capsule contains:</b> Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As Film Coated Tablet Form) Aspirin IP 75mg (As Enteric Coated Tablet Form)	1 Capsule	M/s Pure & Cure Healthcare Pvt. Ltd. /M/s J. B. Chemicals & Pharmcaeuticals Ltd.	2.68
4(xxxii)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 6.25mg Metoprolol Succinate IP 23.75mg eq. to	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s IPCA Laboratories Limited	9.86

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Metoprolol Tartrate (as extended release) 25mg			
4(xxxiii)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s IPCA Laboratories Limited	10.88
4(xxxiv)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 6.25mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s IPCA Laboratories Limited	10.81
4(xxxv)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s IPCA Laboratories Limited	12.91
4(xxxvi)	Escitalopram Oxalate + Clonazepam Tablet	<b>Each film coated tablet contains:</b> Escitalopram Oxalate IP eq. to Escitalopram 5mg, Clonazepam IP 0.5mg	1 Tablet	M/s Windlas Biotech Limited / M/s Mankind Pharma Ltd.	7.81
4(xxxvii)	Escitalopram Oxalate + Clonazepam Tablet	<b>Each film coated tablet contains:</b> Escitalopram	1 Tablet	M/s Windlas Biotech Limited / M/s Mankind	9.56 (Note 2)



S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Oxalate IP eq. to Escitalopram 10mg, Clonazepam IP 0.25mg		Pharma Ltd.	
4(xxxviii)	Escitalopram Oxalate + Clonazepam Tablet	<b>Each film coated tablet contains:</b> Escitalopram Oxalate IP eq. to Escitalopram 20mg Clonazepam IP 0.5mg	1 Tablet	M/s Micro Labs Limited	19.92 (Note 2)
4(xxxix)	Escitalopram Oxalate + Clonazepam Tablet	<b>Each film coated tablet contains:</b> Escitalopram Oxalate IP eq. to Escitalopram 5mg Clonazepam IP 0.5mg	1 Tablet	M/s Micro Labs Limited	7.90
4(xl)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s Intas Pharmaceuticals Limited	12.91
4(xli)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. /M/s Intas Pharmaceuticals Limited	10.88
4(xlii)	Cilnidipine, Telmisartan & Chlorthalidone Tablets	<b>Each film coated tablet contains:</b> Cilnidipine IP 10mg Telmisartan IP 40mg Chlorthalidone IP 12.5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / Dr. Reddy's Laboratories Ltd.	12.946 (Note 2)
	Formoterol	<b>Each hard gelatin</b>	1	M/s Biodeal	7.10

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xliii)	Fumarate + Budesonide Powder for Inhalation	<b>Capsule contains:</b> Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12mcg Budesonide IP 400mcg	Capsule	Pharmaceuticals Pvt. Ltd./ M/s Mankind Pharma Limited	(Note 2)
4(xliv)	Omeprazole (Delayed-Release) + Domperidone (Sustained Release) Capsule	<b>Each hard gelatin capsule contains:</b> Omeprazole IP 20mg (as enteric coated pellets) Domperidone IP 30mg (as sustained release pellets)	1 Capsule	M/s. Eris Lifesciences Ltd. / M/s Eris Healthcare Pvt. Ltd.	8.53
4(xlv)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Limited	12.91
4(xlvi)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	<b>Each film coated bilayered tablet contains:</b> Telmisartan IP 40mg, Chlorthalidone IP 12.50mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Limited	10.88
4(xlvii)	Hydroxychloroquine Tablet	Each film coated tablet contains: Hydroxychloroquine Sulphate IP 300 mg	1 Tablet	M/s Ravenbhel Biotech / M/s Torrent Pharmaceuticals Limited	12.55
4(xlviii)	Beclomethasone Dipropionate + Clotrimazole Cream base	<b>Cream contains:</b> Beclomethasone Dipropionate IP 0.025% w/w, Clotrimazole IP 1.0%w/w,	1 Gram	M/s Curetech Skincare / M/s J. B. Chemicals & Pharmaceuticals Ltd.	5.20

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xlix)	Atorvastatin + Aspirin Capsule	<b>Each hard gelatine capsule contains:</b> Atorvastatin Calcium IP eq. to Atorvastatin 20mg Aspirin IP 75mg (As gastro-resistant tablet IP)	1 Capsule	M/s Tristar Formulations Pvt. Ltd. /M/s Lupin Limited	2.76
4(l)	Atorvastatin + Aspirin Capsule	<b>Each hard gelatin capsule contains:</b> Atorvastatin Calcium IP eq. to Atorvastatin 20mg Aspirin IP 150mg (As two gastro-resistant tablet IP each containing 75mg of Aspirin)	1 Capsule	M/s Tristar Formulations Pvt. Ltd. /M/s Lupin Limited	3.11
4(li)	Ondansetron fast dissolving strip	<b>Each fast dissolving Strip contains:</b> Ondansetron 4mg	1 Strip	M/s Amenan Therapeutics Pvt. Ltd. / M/s Delvin Formulation Pvt. Ltd.	8.13

**Note 1.** The retail prices are to be notified after 10 working days from uploading of draft working sheet/Minutes of the Multidisciplinary Committee of Experts/ Minutes of the Authority Meeting on NPPA's website, as applicable.

**Note 2.** The representative of DCGI present in the meeting confirmed that the formulations are approved by DCGI.

**Note 3.** The Authority noted that M/s Ajanta Pharma Ltd had launched the formulations on November 2017 which is prior to the application for retail price being filed by the company. The Authority further noted that the Multidisciplinary Committee of Experts in its 36<sup>th</sup> meeting dated 11.10.2021 recommended the retail price based on the data available for the month of April 2017 i.e. six month prior to the launch of the formulation by M/s Ajanta Pharma Ltd. The Authority deliberated upon the matter in detail and accepted the recommendation of the Committee.

**Note 4.** The Authority noted the representation of M/s Sun Pharmaceutical Industries Ltd and decided to refer the matter back to the Multidisciplinary Committee of Experts for examination of the representation.

**4.2 Agenda item no. 4A - Retail price fixation under Para 5 of DPCO, 2013 - Each film coated bilayered tablet containing Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Metformin Hydrochloride IP (as extended release).**

4.2.1 The Authority noted that retail price in respect of Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride IP (as extended release) tablets for various companies were fixed based on Form-V data in line with the decision taken in the 72<sup>nd</sup> Authority meeting held on 20.01.2020. The Authority further noted its observations made in the 92<sup>nd</sup> meeting that fixation of retail price of off-patented drugs based on market based data as per AWACS database, in respect of drugs whose retail price has been fixed based on Form-V data for a considerable period, may be explored.

4.2.2 The Authority deliberated upon the matter in detail and observed that further analysis with respect to the price movement of drugs which became off-patent other than Dapagliflozin needs to be done. In view of the above, the Authority decided that the retail price of the Fixed Dose Combinations (FDCs) of Dapagliflozin and Metformin Hydrochloride IP (as extended release) tablets for various companies be continued to be fixed in line with the decisions taken and recorded in Note 2 of Para 4.1 of the Minutes of the 82<sup>nd</sup> Authority meeting dated 23.12.2020. Accordingly, the Authority decided to approve the retail price of FDCs of Dapagliflozin and Metformin Hydrochloride IP (as extended release) tablets for various companies as detailed below:

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Panacea Biotec Pharma Ltd	6.38
2.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Panacea Biotec Pharma Ltd	7.35
3.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg,	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Panacea Biotec Pharma Ltd	11.07

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Metformin Hydrochloride IP 1000mg (As Extended release form)			
4.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Panacea Biotec Pharma Ltd	9.58
5.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Anthem Biopharma Pvt. Ltd	9.58
6.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Troikaa Pharmaceuticals Ltd.	9.58
7.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Troikaa Pharmaceuticals Ltd.	11.07
8.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	9.38
9.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	11.07

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
10.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Limited	11.07
11.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Cadila Pharmaceuticals Limited	9.58
12.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Morepen Laboratories Ltd.	6.25
13.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Morepen Laboratories Ltd.	9.58
14.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Morepen Laboratories Ltd.	7.35
15.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated bilayered tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)	1 Tablet	M/s Morepen Laboratories Ltd.	11.07
16.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	11.07

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	form) Tablet	Dapagliflozin 10mg, Metformin Hydrochloride IP 1000mg (As Extended release form)			
17.	Dapagliflozin + Metformin Hydrochloride (As Extended release form) Tablet	<b>Each film-coated tablet contains:</b> Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg, Metformin Hydrochloride IP 500mg (As Extended release form)	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	9.58

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

5.1 Noted.

**6. Agenda item no. 6 – Fixation of Ceiling Price of scheduled formulations under DPCO 2013 (NLEM 2015)**

6.1 The Authority deliberated upon the matter in detail and approved the ceiling price of Methylthioninium chloride (Methylene blue) 10mg/ml Injection at Rs. 21.85 per ml excluding GST and Hydroxocobalamin Injection 1 mg/ml at Rs. 9.91 per ml excluding GST.

**7. Agenda item no. 7 - Minutes of 36th meeting of Multidisciplinary Committee of Experts held on 11.10.2021 and representations thereon**

7.1 Noted.

7.2 The Authority also observed the representations of M/s Zydus Healthcare Ltd. The Authority deliberated upon the matter in detail and decided that Clotrimazole 1% mouth paint is a scheduled formulation based on Explanation I of DPCO 2013. The Authority further decided to fix the ceiling price of Clotrimazole 1% mouth paint.

**8. Agenda item no. 8 – Reporting of Stock related Submissions Quarterly instead of monthly for capped medical devices**

8.1 The Authority deliberated upon the matter in detail and decided that the submission of information relating to stock details of medical devices namely, (i) Bare Metal Stents, (ii) Drug Eluting Stent, (iii) Orthopaedic Knee Implants, and (iv) Oxygen Concentrators may be reported on a quarterly basis instead of monthly.



**9. Agenda item no. 9 – Notification SO. No. 2161(E) dated 03.06.2021 relating to price regulation of Oxygen Concentrators based on Trade Margin Rationalisation (TMR) approach**

9.1 The Authority noted that the notification SO. No. 2161(E) dated 03.06.2021 relating to price regulation of Oxygen Concentrators based on Trade Margin Rationalisation (TMR) approach is applicable upto 30.11.2021. The Authority also noted the recommendation of Standing Committee on Affordable Medicines and Health Products (SCAMHP) in its 4<sup>th</sup> and 5<sup>th</sup> meeting held on 25.05.2021 and 30.05.2021 respectively. The Authority deliberated upon the matter in detail and was of the opinion that as COVID pandemic is still a risk to public health; availability of Oxygen Concentrators at affordable prices must be ensured. Hence, it was decided that the notification be extended, before it expires, for another six months upto 30.05.2022. The Authority further decided that the matter be forwarded to SCAMHP for its recommendations.


**10. Agenda item no. 10 - Form-IV intimation received from M/s Serum Institute of India Pvt. Ltd in respect of 2 scheduled formulations (i) Tetanus Toxoid Injection 0.5ml and (ii) Tetanus Toxoid Injection 5 ml of M/s Serum Institute of India Pvt. Ltd**

10.1 The Authority deliberated upon the matter in detail and decided that Para 3 of DPCO 2013 be invoked in relation to M/s Serum Institute of India Pvt. Ltd for 2 scheduled formulations (i) Tetanus Toxoid Injection in 0.5ml pack and (ii) Tetanus Toxoid Injection in 5 ml pack for further period of six month i.e upto 22<sup>nd</sup> June, 2022.

**11. Agenda item no. 11 – Form-IV intimation received from M/s Neon Laboratories Limited for discontinuation of scheduled formulation viz., Lox 5% Ointment (Lidocaine 5%) under Para 21(2) of DPCO, 2013**

11.1 The Authority deliberated upon the matter in detail and decided not to allow discontinuation of scheduled formulation Lidocaine 5% (Lox 5%) of M/s Neon Laboratories Ltd.

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

  
**(Dr. Vinod Kotwal)**  
Member Secretary