

Minutes of the 227th (overall) and 95th meeting of the Authority under DPCO, 2013 held on 28.01.2022 at 3:30 PM

The 227th meeting of the Authority (overall), which is the 95th meeting under the DPCO, 2013, was held on 28th January 2022 at 3:30 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) Dr. V. G. Somani, Drug Controller General of India through Video Conferencing
- (iii) Shri Amardeep Singh Chowdhary, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure 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) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (ii) Shri G. L. Gupta, Director (Monitoring)
- (iii) Shri Prasenjit Das, Deputy Director (Pricing)
- (iv) Shri Mahaveer Saini, Deputy Director (Pricing)
- (v) Shri Rajesh Kumar T., Deputy Director (Medical Device, Legal&IT)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 94th Meeting held on 23.12.2021

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 - Action Taken Report (ATR) on decisions taken by NPPA in its 94th Meeting held on 23.12.2021

2.1 The Authority noted that due action has been taken.

2.2 A presentation on the Pricing Methodology was made before the Authority members highlighting the various aspects of Pricing Mechanism as per DPCO 2013.

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

3.1 Noted.

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(xx) (total 20 Form I applications containing retail price fixation of 20 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 20 (twenty) 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)	Paracetamol + Phenylephrine + Caffeine+ Diphenhydramine Tablet	Each film coated tablet contains: Paracetamol IP 500 mg + Phenylephrine Hydrochloride IP 5 mg + Caffeine (anhydrous) 30 mg + Diphenhydramine Hydrochloride IP 25 mg	1 Tablet	M/s Mediforce Healthcare Pvt. Ltd./ M/s Mankind Prime Labs Pvt. Ltd.	3.21
4(ii)	Gliclazide ER + Metformin ER Tablet	Each uncoated bilayered tablet contains: Gliclazide IP (as extended release form) 60mg Metformin Hydrochloride IP (As extended release form) 1000mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Eris Lifesciences Limited	8.54
4(iii)	Chlorthalidone + Telmisartan + Amlodipine Tablet	Each film coated tablet contains: Chlorthalidone IP 6.25mg Telmisartan IP 40mg Amlodipine Besilate IP eq. to Amlodipine 5mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences / M/s USV Pvt. Ltd.	8.92 (Note 2)
4(iv)	Telmisartan + Cilnidipine Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg Cilnidipine IP 10mg	1 Tablet	M/sWindlas Biotech Pvt. Ltd. / M/s USV Pvt. Ltd.	9.66
4(v)	Gliclazide + Metformin Hydrochloride (Each uncoated bilayered sustained release tablet contains:	1 Tablet	M/s Windlas Biotech Pvt. Ltd. / Panacea Biotec	8.54

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Sustained release) Tablet	Gliclazide IP 60 mg Metformin Hydrochloride IP 1000 mg		Pharma Ltd	
4(vi)	Atorvastatin & Clopidogrel Capsule	Each hard Gelatin Capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20mg (As two Film Coated Tablets Each containing Atorvastatin 10mg) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two film coated tablets Each containing 37.5 mg Clopidogrel)	1 Capsule	M/s Windlas Biotech Limited / M/s Torrent Pharmaceuticals Limited	16.70
4(vii)	Telmisartan, Cilnidipine & Metoprolol (ER) Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40mg Cilnidipine IP 10mg Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (as extended release) 25mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Alkem Laboratories Limited	10.68
4(viii)	Telmisartan, Cilnidipine & Metoprolol (ER) Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40mg Cilnidipine IP 10mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (as extended release) 50mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Alkem Laboratories Limited	12.95
4(ix)	Metformin + Glimepiride Tablet	Each Uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg (as Prolonged-Release) Glimepiride IP 2mg	1 Tablet	M/s Associated Biotech / M/s Dales Laboratories	7.59
4(x)	Atorvastatin & Clopidogrel Capsule	Each hard Gelatin Capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10mg (As Film Coated Tablet) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two film coated tablets) Each containing 37.5 mg Clopidogrel	1 Capsule	M/s Windlas Biotech Limited / M/s Torrent Pharmaceuticals Limited	12.55

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xi)	Diclofenac Tablet	Each film coated prolonged release tablet contains: Diclofenac Sodium IP 100mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Alembic Pharmaceuticals Ltd.	6.68
4(xii)	Metformin + Glimepiride Tablet	Each Uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg (as Prolonged-Release) Glimepiride IP 1mg	1 Tablet	M/s Associated Biotech / M/s Dales Laboratories	6.25
4(xiii)	Metformin (Extended-Release) + Teneligliptin Tablet	Each Uncoated bilayered tablet contains: Metformin Hydrochloride IP 500mg (as Extended-Release) Teneligliptin Hydrobromide Hydrate eq. to Teneligliptin 20mg	1 Tablet	M/s Associated Biotech / M/s Dales Laboratories	7.14
4(xiv)	Telmisartan + Amlodipine + Hydrochlorothiazide Tablet	Each film coated tablet contains: Telmisartan IP 40 mg + Amlodipine Besilate IP eq. to Amlodipine 5mg + Hydrochlorothiazide IP 12.5 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticlas Ltd.	9.79
4(xv)	Paracetamol + Thiocolchicoside Tablet	Each uncoated tablet contains: Paracetamol IP 500 mg Thiocolchicoside IP 4 mg	1 Tablet	M/s Micro Labs Limited	16.94
4(xvi)	Pantoprazole Dual-release Gastro-resistant tablet (Aristo Pantop 80)	Each Dual-release Gastro-resistant tablet contains: Pantoprazole Sodium IP eq. to Pantoprazole 80 mg	1 Tablet	M/s Aristo Pharmaceuticals Pvt. Ltd.	14.74
4(xvii)	Calcium, Vitamin D3, Mecobalamin, L-Methylfolate Calcium & Pyridoxal-5-Phosphate Tablet	Each film coated tablet contains: Calcium Carbonate IP 1250mg eq. to Elemental Calcium 500mg Vitamin D3 IP 2000IU Mecobalamin IP (Methylcobalamin) 1500mcg L-Methylfolate Calcium 1mg Pyridoxal-5-Phosphate 20mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	15.55

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xviii)	Diclofenac Transdermal Patch	Each 37.5 Sq cm Transdermal Patch contains: Diclofenac Diethylamine IP 100mg	1 Patch	M/s Azista Industries Pvt. Ltd. / M/s Hetero Healthcare Ltd.	31.25
4(xix)	Diclofenac Diethylamine + Methyl Salicylate + Menthol topical Spray	Composition: Diclofenac Diethylamine IP 2.32% w/w (Eq. to Diclofenac Sodium 2% w/w) Methyl Salicylate IP 10% w/w Menthol IP 5% w/w	1 Gram	M/s Pontika Aerotech Limited / M/s Intas Pharmaceuticals Limited	2.93
4(xx)	Paracetamol Infusion	Each 100ml contains: Paracetamol 1.0% w/v (10mg/ml)	1 ML	M/s Axa Parenterals Limited / M/s Aristo Pharmaceuticals Pvt. Limited	3.05

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.

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

5.1 Noted.

6. Agenda item no. 6 – Form-IV Intimation by M/s Neon Laboratories Limited in respect of scheduled formulation Tropine 1ml Injection (Atropine Sulphate Injection 0.6mg/ml) under para 21(2) of DPCO, 2013

6.1 The Authority deliberated upon the matter in detail and decided that Para 3 of DPCO 2013 be invoked in relation to M/s Neon Laboratories Ltd for the scheduled formulation Atropine Injection 0.6mg/ml for further period of six month i.e. upto 05.08.2022.

7. Agenda item no. 7 - Regulation of Price of Medical Devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer

7.1 The Authority noted that the notification SO. No. 2808(E) dated 13.07.2021 relating to price regulation of Medical Devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer based on Trade Margin Rationalisation (TMR) approach is applicable upto 31.01.2022.

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 Medical Devices, namely, (i) Pulse Oximeter, (ii) Blood Pressure Monitoring Machine, (iii) Nebulizer, (iv) Digital Thermometer, and (v) Glucometer at affordable prices must be ensured. Hence, it was decided that the notification be extended, before it expires, for another six months upto 31.07.2022.

8. Agenda item no. 8 - Minutes of the 38th meeting of the Multidisciplinary Committee of Experts held on 24.01.2022 at 3:30 PM.

8.1 Noted.

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

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(Dr. Vinod Kotwal)
Member Secretary