

Minutes of the 226th (overall) and 94th meeting of the Authority under DPCO, 2013 held on 23.12.2021 at 11:30 AM

The 226th meeting of the Authority (overall), which is the 94th meeting under the DPCO, 2013, was held on 23rd of December 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) 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

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 S. S. Ojha, Jt. Director (Pricing)
- (ii) Shri Prasenjit Das, Deputy Director (Pricing)
- (iii) Shri Mahaveer Saini, Deputy Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of the Minutes of the 93rd Meeting held on 15.11.2021.

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 - Action Taken Report on minutes of the 225th (overall) and 93rd meeting of the Authority under DPCO 2013 held on 15.11.2021 at 11:30 AM

2.1 The Authority noted that due action has been taken.

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(xxix) (total 29 Form I applications containing retail price fixation of 29 new drugs) falling under the purview of Para 2(u) of DPCO, 2013 and approved the retail prices of 28 (twenty eight) 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)	Cyclosporine Ophthalmic Solution	Each ml contains: Cyclosporine IP 0.09mg Aqueous Buffered Vehicle q.s.	Each 0.25ml Pack	M/s Sun Pharmaceutical Industries Limited	51.29
4(ii)	Amoxicillin + Potassium Clavulanate Oral Suspension IP	Each 5ml of reconstituted suspension contains: Amoxicillin Trihydrate eq. to Amoxicillin IP 600mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg	1 ml	M/s Alkem Healthscience / M/s Alkem Laboratories Ltd.	3.36
4(iii)	Povidone-Iodine + Ornidazole Ointment	Composition: Povidone-Iodine IP 5%w/w (Available Iodine 0.5%w/w) Ornidazole IP 1% w/w In an Ointment base	1 gm	M/s Innova Captab Ltd. / M/s Emcure Pharmaceuticals Ltd.	3.78
4(iv)	Povidone Iodine Topical Solution	Each 100ml solution contains: Povidone Iodine IP 1.0g (Available Iodine 0.1 g) 2-Propanol IP 50g	Each Pack (500ml)	M/s GS Pharmabutor Pvt. Ltd. / M/s Win Medicare Pvt. Ltd.	230.00
4(v)	Atorvastatin + Clopidogrel Capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq to Atorvastatin 40mg (As green coloured spherical pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two brown coloured film coated	1 Capsule	M/s Windlas Biotech Pvt. Limited / M/s Intas Pharmaceuticals Ltd.	28.08

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		tablets Each containing 37.5mg Clopidogrel Tablets IP)			
4(vi)	Diclofenac Diethylamine + Methyl Salicylate + Menthol Gel	Gel contains: Diclofenac Diethylamine IP 2.32% w/w (equivalent to Diclofenac Sodium IP 2.0% w/w) Methyl Salicylate IP 10% w/w Menthol IP 5% w/w	1 gm	M/s Tuton Pharmaceuticals /M/s Unison Pharmaceuticals Pvt. Ltd.	3.69
4(vii)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: 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 Sun Pharma Laboratories Limited	9.86
4(viii)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: 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 Sun Pharma Laboratories Limited	10.81
4(ix)	Atorvastatin + Clopidogrel + Aspirin Capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 40mg (As coloured pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two brown coloured film coated tablet each containing 37.5mg clopidogrel tablet IP), Aspirin IP 75mg (As enteric coated white coloured pellets)	1 Capsule	M/s Windlas Biotech Limited / M/s Torrent Pharmaceuticals Limited	12.92

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S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(x)	Atorvastatin + Clopidogrel + Aspirin Capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 40mg (As coloured pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two reddish brown coloured film coated tablet each containing 37.5mg clopidogrel tablet IP), Aspirin IP 75mg (As enteric coated white coloured pellets)	1 Capsule	M/s Windlas Biotech Pvt. Ltd. / M/s USV Pvt. Ltd.	12.92
4(xi)	Human Normal Immunoglobulin for Intravenous use IP 5% (Ig M Enriched)	Each Vial contains: Total Protein 50 g/L, Immunoglobulin M 6g/L, Immunoglobulin A 6g/L, Immunoglobulin G 38g/L, Glucose Monohydrate (as stabilizer) 27.5g/L, Sodium Chloride 4.56g/L, Water for injection	1 ml	M/s Intas Pharmaceuticals Ltd	(Note3)
4(xii)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: 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 Lupin Limited	9.86
4(xiii)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: 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 Lupin Limited	10.81

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xiv)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: 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 Lupin Limited	11.92
4(xv)	Telmisartan, Chlorthalidone & Metoprolol (ER) Tablet	Each film coated bilayered tablet contains: 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 Lupin Limited	10.88
4(xvi)	Diclofenac injection IP	Each ml contains: Diclofenac Sodium IP 75mg Water for injection IP	1 ml	M/s Nitin Lifesciences Ltd./ M/s Modi-Mundipharma Pvt. Ltd.	20.27
4(xvii)	Amoxycillin + Potassium Clavulanate Oral Suspension IP	Each 5ml of the reconstituted suspension contains: Amoxycillin Trihydrate eq. to Amoxycillin IP 400mg Potassium Clavulanate Diluted IP eq. to Clovulanic Acid 57mg	1 ml	M/s Associated Biotech./ M/s Eris Healthcare Pvt. Limited	3.68
4(xviii)	Mefenamic Acid+ Tranexamic Acid Tablet	Each film coated tablet contains: Mefenamic Acid IP 250mg Tranexamic Acid IP 500mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Eris Healthcare Pvt. Limited	26.12
4(xix)	Atorvastatin + Clopidogrel Capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 40mg (As green coloured spherical pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel	1 Capsule	M/s Windlas Biotech Limited / M/s Torrent Pharmaceuticals Limited	28.08

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		75mg (As two brown coloured film coated tablets Each containing 37.5mg Clopidogrel Tablets IP)			
4(xx)	Glimepiride + Metformin Hydrochloride + (Sustained Release) + Voglibose Tablet	Each uncoated bilayer tablet contains : Glimepiride IP - 1 mg Metformin Hydrochloride IP - 500 mg (Sustained Release Form) Voglibose IP - 0.2 mg	1 Tablet	M/s Theon Pharmaceuticals Limited / M/s FDC Limited	9.82
4(xxi)	Metoprolol Succinate prolonged Released Tablets IP	Each film coated prolonged release tablet contains: Metoprolol Succinate IP 95mg eq. to Metoprolol Tartrate 100mg	1 Tablet	M/s Micro Labs Limited	11.38
4(xxii)	Glimepiride I+ Metformin Hydrochloride + (Sustained Release) + Voglibose Tablet	Each uncoated bilayer tablet contains : Glimepiride IP - 2 mg Metformin Hydrochloride IP - 500 mg (Sustained Release Form) Voglibose IP - 0.2 mg	1 Tablet	M/s Theon Pharmaceuticals Limited / M/s FDC Limited	12.50
4(xxiii)	Clobazam Mouth Dissolving tablet	Each uncoated Mouth Dissolving tablet contains: Clobazam IP 2.5mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. / M/s Intas Pharmaceuticals Limited	2.54
4(xxiv)	Acetylcysteine + Acebrophylline Tablet	Each film coated tablet contains: Acetylcysteine BP 600mg Acebrophylline 100mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/ Cipla limited	12.48 (Note 4)
4(xxv)	Levetiracetam Tablet IP	Each film coated tablet contains: Levetiracetam IP 1000mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	29.87
4(xxvi)	Levetiracetam Tablet IP	Each film coated tablet contains: Levetiracetam IP 1000mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd. / M/s Wockhardt Limited	26.70

S. No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4(xxvii)	Glycopyrronium + Formoterol Fumarate + Budesonide Powder for Inhalation	Each capsule contains: Glycopyrrolate IP eq. to Glycopyrronium 25mcg Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 12mcg Budesonide IP 400mcg	1 Capsule	M/s Zydus Healthcare Limited	12.64
4(xxviii)	Esomeprazole + Domperidone SR Capsule	Each hard Gelatin Capsule Contains: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg (as gastro-resistant pellets) Domperidone IP 30mg (as sustained release pellets)	1 Capsule	M/s Indu Drugs Private Limited	10.70
4(xxix)	Atorvastatin + Clopidogrel Capsule	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 40mg (As green coloured spherical pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two brown coloured film coated tablets Each containing 37.5mg Clopidogrel Tablets IP),	1 Capsule	M/s Windlas Biotech Limited / M/s Zydus Healthcare Pvt. Ltd.	30.74

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 the representation received from M/s Intas Pharmaceutical Ltd and decided that the matter be referred to Multidisciplinary Committee of Experts for examination.

Note 4. The Authority noted that M/s Cipla Ltd have launched the product in February 2020 without prior price approval. Accordingly, the Authority decided that the retail price of the formulation for M/s Cipla Ltd to be calculated based on the data which is six month

prior to its launch date i.e. July 2019. The Authority also decided further necessary action be initiated for violation of the provisions of DPCO 2013 for launching the formulation without prior price approval.

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

5.1 Noted.

6. Agenda item no. 6 – Application by M/s Denis Chem Lab Ltd. for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v 100 ml (ii) Mannitol injection 20% 100 ml (iii) Metronidazole Injection IP (0.5% w/v) 100ml in Non-glass pack having Special features.

6.1 The Authority deliberated upon the matter in detail and noted that M/s Denis Chem Lab Ltd have applied for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack in line with S.O. 3939(E) dated 23.09.2021; S.O. 3938(E) dated 23.09.2021; and SO. 3937(E) dated 23.09.2021 respectively.

6.2 The Authority further noted that the matter was deliberated in the 37th meeting of the Multidisciplinary Committee of Experts held on 25.11.2021 and M/s Denis Chem Lab Ltd had demonstrated before the Multidisciplinary Committee of Experts and the Committee observed that (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack of M/s Denis Chem Lab Ltd have special features as (i) self collapsibility and self-seal ability, (ii) not having air-vent, and (iii) having no chance of contamination during manufacture / infusion / admixing levels. The Authority also noted that the Committee has recommended extending the ceiling prices and the formulations mentioned in S.O. 3939(E) dated 23.09.2021; S.O. 3938(E) dated 23.09.2021; and SO. 3937(E) dated 23.09.2021 to M/s Denis Chem Lab Ltd for (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack respectively.

6.3 Accordingly, the Authority decided to extend the ceiling prices mentioned in S.O. 3939(E) dated 23.09.2021, S.O. 3938(E) dated 23.09.2021 and SO. 3937(E) dated 23.09.2021 for the formulations (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack respectively to M/s Denis Chem Lab Ltd as the formulations having packages with special features like (i) self

collapsibility and self seal ability, (ii) not having air-vent, and (iii) having no chance of contamination during manufacture / infusion / admixing levels.

7. Agenda item no. 7 - Application by M/s Rosuma Laboratories Pvt. Ltd. for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v 100 ml (ii) Mannitol injection 20% 100 ml (iii) Metronidazole Injection IP (0.5% w/v) 100ml in Non-glass pack having Special features.

7.1 The Authority deliberated upon the matter in detail and noted that M/s Rosuma Laboratories Pvt. Ltd have applied for separate price under Para 11(3) of DPCO 2013 with respect to (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack in line with S.O. 3939(E) dated 23.09.2021; S.O. 3938(E) dated 23.09.2021; and SO. 3937(E) dated 23.09.2021 respectively.

7.2 The Authority further noted that the matter was deliberated in the 37th meeting of the Multidisciplinary Committee of Experts held on 25.11.2021 and M/s Rosuma Laboratories Pvt. Ltd had demonstrated before the Multidisciplinary Committee of Experts and the Committee had observed that (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack of M/s Rosuma Laboratories Pvt. Ltd have special features as (i) self collapsibility and self-seal ability, (ii) not having air-vent, and (iii) having no chance of contamination during manufacture / infusion / admixing levels. The Authority also noted that the Committee recommended extending the ceiling prices and the formulations mentioned in S.O. 3939(E) dated 23.09.2021; S.O. 3938(E) dated 23.09.2021; and SO. 3937(E) dated 23.09.2021 to M/s Rosuma Laboratories Pvt. Ltd for (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack respectively.

7.3 Accordingly, the Authority decided to extend the ceiling prices mentioned in S.O. 3939(E) dated 23.09.2021, S.O. 3938(E) dated 23.09.2021 and SO. 3937(E) dated 23.09.2021 for the formulations (i) Dextrose Injection 25%w/v in Non-glass pack having Special features for 100 ml pack (ii) Mannitol injection 20% in Non-glass pack having Special features for 100 ml pack (iii) Metronidazole Injection IP (0.5% w/v) in Non-glass pack having Special features for 100 ml pack respectively to M/s Rosuma Laboratories Pvt. Ltd as the formulations having packages with special features like (i) self collapsibility and self seal ability, (ii) not having air-vent and (iii) having no chance of contamination during manufacture / infusion / admixing levels.



8. Agenda item no. 8 – Extension of revised price of Medical Oxygen.

8.1 The Authority noted that the price fixed for Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder vide SO. 3322(E) dated 25.09.2020 are applicable up to 31.03.2021 and was further extended upto 30.09.2021 or until further order, whichever is earlier, vide SO. 1335(E) dated 25.03.2021 and again extended upto 31.12.2021 or until further order, whichever is earlier, vide SO. 3936(E) dated 23.09.2021.

8.2 The Authority further noted that Department for Promotion of Industry & Internal Trade (DPIIT), Ministry of Commerce and Industry, Government of India vide its Office Memorandum dated 23.12.2021 stated as follows:

“...the matter has been examined in this Department and in view of the necessity to remain vigilant against threat of COVID 19 and its new variant Omicron, it is recommended that the prices of above drugs may further be extended by another three months beyond 31.12.2021, after which the issue may be reviewed again.”

8.3 The Authority deliberated upon the matter in detail and in view of continuing extraordinary circumstances due to the COVID pandemic decided that the revised price of Liquid Medical Oxygen (LMO) and Oxygen Inhalation (Medicinal gas) in cylinder fixed vide SO. 3322(E) dated 25.09.2020 and extended vide SO. 1335(E) dated 25.03.2021 and SO. 3936(E) dated 23.09.2021 be further extended up to 31.03.2022 or until further order, whichever is earlier, in public interest.

9. Agenda item no. 9 - Fixation of Ceiling Price of (i) Clotrimazole 1% mouth paint and (ii) Water for Injection in 500 ml and 1000 ml pack under DPCO 2013 (NLEM 2015).

9.1 The Authority noted the representation of M/s Zydus Healthcare Ltd regarding the ceiling price fixation of Clotrimazole 1% mouth paint. The Authority deliberated upon the matter in detail and decided that the matter may be referred to the Multidisciplinary Committee of Experts to examine the representation of M/s Zydus Healthcare Ltd.

9.2 The Authority deliberated upon the matter in detail and decided to approve the ceiling price of Water for injection in 500 ml pack and 1000ml pack at Rs. 46.21 per 500 ml pack excluding GST and Rs. 81.11 per 1000 ml pack excluding GST respectively.

10. Agenda item no. 10 – Minutes of 36th meeting of Multidisciplinary Committee of Experts held on 11.10.2021 and representations thereon

10.1 Noted.

11. Agenda item no. 11 - Regularization of Existing formulation based on the Recommendations of DTAB

11.1 The Authority noted the representation of M/s Abbott Healthcare Ltd and decided that M/s Abbott Healthcare be directed to seek approval for retail price of the formulation "Fixed Dose Combination (FDC) of Cefixime 200 mg + Dicloxacillin 500 mg Ext. Release + Lactic Acid Bacillus 2.5 billion Spores tablet" prior to its launch in accordance with the provisions of DPCO 2013.

12. Agenda item no. 12 - Other issues

12.1 The Authority further opined that a presentation on the pricing mechanism may be made before the Authority in the next meeting.

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

बि.कोतवाल
(Dr. Vinod Kotwal)
Member Secretary