

मिसिल स.- 8(143)/2026/डी.पी/एनपीपीए-डीवी-II

F. No. 8(143)/2026/DP/NPPA-Div. II

कार्यवाही स. : 275/143/2026/F

Proceeding No: 275/143/2026/F

Minutes of the 275th (overall) and 143rd meeting of the Authority under DPCO, 2013 held on 27.02.2026 at 12:00 PM.

The 275th meeting of the Authority (overall), which is the 143rd meeting under the DPCO, 2013 was held on 27th February, 2026 at 12:00 PM under the Chairmanship of Shri P. Krishnamurthy, Chairman, NPPA. The following Authority members were present during the meeting:

- (i) Ms. Sai Ahlladini Panda, Member Secretary, NPPA
- (ii) Shri Vijay Kumar, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

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, Adviser (Cost)
- (ii) Shri Aman Bharti, Director (M&E)
- (iii) Ms. Rashmi Tahiliani, Director (Pricing)
- (iv) Ms. Priyanka Sachdeva, Joint Director (Pricing)
- (v) Shri Mahaveer Saini, Joint Director (Pricing) - Additional Charge
- (vi) Ms. Yuvika Panwar, Deputy Director (Pricing) - Additional Charge
- (vii) Shri Bhiva Ram Yadav, Assistant Director (Pricing)
- (viii) Shri Devanshu Gupta, Assistant Director (Pricing)
- (ix) Shri Mayur Panwar, Assistant Director (Pricing)

1. Agenda item no. 1 - Confirmation of the Minutes of the 142nd Meeting held on 30.01.2026.

1.1 The Authority confirmed the minutes of the meeting without any change.

2. Agenda item no. 2 - Action Taken Report (ATR) on decisions taken by NPPA in its 142nd Meeting held on 30.01.2026.

2.1 Noted.

3. Agenda item no. 3 - Status of new drug application.

3.1 Noted.

4. Agenda item no. 4 – New Drug application for price fixation under Paragraph 5 and 15 of DPCO, 2013.

4.1 The Authority deliberated on 20 (Twenty) cases of retail price fixation of new drugs as presented in Agenda no. 4(1) to 4(20) falling under the purview of paragraph 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of 20 (Twenty) new drugs under paragraph 5 and 15 of DPCO, 2013 as given in **Table 1 below:**

Table No. 1: Retail price fixation of new drugs

Sl. No.	Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	4(1)	Atorvastatin and Clopidogrel Capsules	Each hard gelatin capsule contains: Atorvastatin Calcium IP Equivalent to Atorvastatin 40 mg (as pellets) Clopidogrel Bisulphate IP Equivalent to Clopidogrel 75 mg (as pellets)	1 Capsule	M/s Macleods Pharmaceuticals Ltd.	30.09
2	4(2)	Atorvastatin, Clopidogrel and Aspirin Capsules	Each Hard Gelatin Capsule Contains: Atorvastatin Calcium IP Eq. to Atorvastatin 10 mg (As Film Coated Atorvastatin Tablets IP) Clopidogrel Bisulphate IP Eq. to Clopidogrel 75 mg (As Film Coated Clopidogrel Tablets IP) Aspirin IP 75mg (As Aspirin Gastro-Resistant Tablets IP)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd.	6.19
3	4(3)	Atorvastatin, Clopidogrel and Aspirin Capsules	Each Hard Gelatin Capsule Contains: Atorvastatin Calcium IP Eq. to Atorvastatin 20 mg (As Film Coated Atorvastatin Tablets IP) Clopidogrel Bisulphate IP Eq. to Clopidogrel 75 mg (As Film Coated Clopidogrel Tablets IP) Aspirin IP 75mg (As Aspirin Gastro-Resistant Tablets IP)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd.	8.80

Sl. No.	Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
4	4(4)	Bilastine & Montelukast Oral Suspension	Each 5 ml Suspension Contains: Bilastine IP 10 mg Montelukast Sodium IP eq. to Montelukast 4 mg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Hetero Healthcare Ltd.	1.75
5	4(5)	Bisoprolol Fumarate & Telmisartan Tablets	Each uncoated bilayered tablet contains: Bisoprolol Fumarate IP 2.5 mg Telmisartan IP 40 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Alkem Wellness Ltd.	10.73
6	4(6)	Bisoprolol Fumarate & Telmisartan Tablets	Each uncoated bilayered tablet contains: Bisoprolol Fumarate IP 5 mg Telmisartan IP 40 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Alkem Wellness Ltd.	12.55
7	4(7)	Cetirizine Ophthalmic Solution	Each ml contains: Cetirizine Hydrochloride IP Eq. to Cetirizine 0.24% w/v Benzalkonium Chloride Solution IP 0.02% v/v (As preservative)	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Micro Labs Ltd.	14.42
8	4(8)	Cetirizine Ophthalmic Solution	Each ml contains: Cetirizine Hydrochloride IP Eq. to Cetirizine 0.24% w/v Benzalkonium Chloride Solution IP 0.02% v/v (As preservative)	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Sun Pharma Laboratories Ltd.	14.42
9	4(9)	Cilnidipine and Telmisartan Tablets	Each film coated tablet contains: Cilnidipine IP 10 mg Telmisartan IP 40 mg	1 Tablet	M/s East African (I) Overseas/ M/s SRK Puremed LLP	8.57
10	4(10)	Dehydroepiandrosterone (DHEA) (Micronized) and Folic Acid Hard Gelatin Capsules	Each Hard Gelatin Capsule Contains: Dehydroepiandrosterone 25 mg (Micronized) Folic Acid IP 1.5 mg	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Mankind Pharma Ltd.	12.42

Sl. No.	Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
11	4(11)	Empagliflozin, Sitagliptin & Metformin Hydrochloride Extended Release Tablets	Each film coated bilayer tablet contains: Empagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100 mg Metformin Hydrochloride (As Extended Release) IP 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Kollectcare Pvt. Ltd.	14.22
12	4(12)	Empagliflozin, Sitagliptin & Metformin Hydrochloride Extended Release Tablets	Each film coated bilayer tablet contains: Empagliflozin 25 mg Sitagliptin Phosphate Monohydrate IP Equivalent to Sitagliptin 100 mg Metformin Hydrochloride (As Extended Release) IP 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Kollectcare Pvt. Ltd.	16.36
13	4(13)	Ivermectin & Albendazole Tablets	Each uncoated chewable tablet contains: Ivermectin IP 6 mg Albendazole IP 400 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s Glensmith Labs Pvt. Ltd.	28.34
14	4(14)	Levofloxacin Eye Drops	Composition: Levofloxacin Hemihydrate IP Eq. to Levofloxacin 0.5% w/v Benzalkonium Chloride 0.005% w/v (as preservative)	1 ml	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	11.60
15	4(15)	Mecobalamin, Alpha Lipoic Acid, Vitamin D3, Pyridoxine Hydrochloride & Folic Acid Tablets	Each film coated tablet contains: Mecobalamin IP 1500 mcg Alpha Lipoic Acid IP 100 mg Vitamin D3 IP 1000 IU Pyridoxine	1 Tablet	M/s JK Print Packs (Pharma Division) / M/s Mankind Prime Labs Pvt. Ltd.	16.62

Sl. No.	Agenda item no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
			Hydrochloride IP 3mg Folic Acid IP 1.5 mg			
16	4(16)	Metoprolol Succinate ER, Cilnidipine & Telmisartan tablets	Each Film Coated Tablet Contains: Metoprolol Succinate IP 47.5 mg Eq. to Metoprolol Tartrate (As Extended Release) 50 mg Cilnidipine IP 10 mg Telmisartan IP 40 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Ipca Laboratories Ltd.	14.35
17	4(17)	Metoprolol Succinate ER, Cilnidipine & Telmisartan tablets	Each Film Coated Tablet Contains: Metoprolol Succinate IP 23.75 mg Eq. to Metoprolol Tartrate 25 mg (As Extended Release) Cilnidipine IP 10 mg Telmisartan IP 40 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Ipca Laboratories Ltd.	11.45
18	4(18)	Rosuvastatin and Clopidogrel Tablets	Each film coated tablet contains: Rosuvastatin Calcium IP eq. to Rosuvastatin 10 mg Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg	1 Tablet	M/s Sun Pharma Laboratories Ltd.	16.32
19	4(19)	Tacrolimus Ointment	Composition: Tacrolimus IP 0.1%w/w	1 gm	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	33.33
20	4(20)	Telmisartan & Cilnidipine Tablets	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s Primus Remedies Pvt. Ltd.	10.00

5. Agenda No. 5: Re-invocation of Para 3 of the DPCO, 2013 i.r.o 4 scheduled formulations viz., (i) Urografin 76%-20ml (ii) Urografin 76%-50ml (iii) Urografin 76%-100ml and (iv) Urografin 60%-20ml containing Meglumine Diatrizoate on M/s Bayer Zydus Pharma



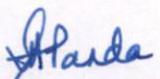
The Authority noted that M/s Bayer Zydus Pharma had requested for discontinuation of their Scheduled formulations (i) Urografin 76%-20ml (ii) Urografin 76%-50ml (iii) Urografin 76%-100ml and (iv) Urografin 60%-20ml containing Meglumine Diatrizoate in Aug, 2021 due to economic unfeasibility and a clinical shift from High Osmolality Contrast Media to Low Osmolality Contrast Media. The matter was examined in the Standing Committee meetings constituted to discuss discontinuation cases along with the Public Health experts and the inputs of the private diagnostic lab representatives were also sought. Based on the inputs from the stakeholders and recommendations of the Standing committee, directions were issued by the Authority under Para 3 of the DPCO, 2013 from time to time and currently the same is in force till 28.02.2026.

2. The Authority deliberated upon the matter in detail and noted that the subject formulation is a hospital supply formulation and, as per the available market-based data, only a limited number of market players are present in the market. It was also observed by Authority that the CDSCO has informed vide email dated 06.02.2026, that the application of company for grant of Registration Certificate is pending at the company's end since 26.08.2025 for submission of response of the query raised by the O/o DCGI w.r.t new drug permission.

3. During the deliberation, the representative of CDSCO clarified that the company should submit the earlier manufacturing permission or licence issued in respect of the subject formulation, for consideration by CDSCO.

4. After detailed deliberation, the Authority decided to re-invoke the directions issued under Paragraph 3 of the DPCO, 2013 to direct M/s Bayer Zydus Pharma to continue the production and sales of the subject scheduled formulations (1) Urografin 76%-20ml (ii) Urografin 76%- 50ml (iii) Urografin 76%-100ml and (iv) Urografin 60%-20ml containing Meglumine Diatrizoate for a period of one year i.e. up to 28.02.2027.

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


(Sai Ahlladini Panda)
Member Secretary