

मिसिल स.- 8(150)/2026/डी.पी/एनपीपीए-डीवी-II

F. No. 8(150)/2026/DP/NPPA-Div. II

कार्यवाही स. : 282/150/2026/F

Proceeding No: 282/150/2026/F

Minutes of the 282nd (overall) and 150th meeting of the Authority under DPCO, 2013 held on 25.08.2026 at 12:30 PM.

The 282nd meeting of the Authority (overall), which is the 150th meeting under the DPCO, 2013 was held on 25.08.2026 at 12:30 PM under the Chairmanship of Shri P. Krishnamurthy, Chairman, NPPA. The following Authority members were present during the meeting:

- (i) Ms. Sai Ahladini Panda, Member Secretary, NPPA
- (ii) Shri Anand Kumar Pal, Chief Adviser (Cost), O/o Chief Adviser Cost, Department of Expenditure
- (iii) Dr. Rose Mary K. Abraham, 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 Rajiv Wadhawan, Adviser (Cost)
- (ii) Ms. Priyanka Sachdeva, Joint Director (Pricing)
- (iii) Shri Bhiva Ram Yadav, Assistant Director (Pricing)
- (iv) Shri Mayur Panwar, Assistant Director (Pricing)

For agenda item no. 11, following officers were also present-

- (i) Shri Santanu Agrahari, Director (M&E)
- (ii) Ms. Manisha Khuntia, Deputy Director (Enf.)

At the outset, Member Secretary, welcomed all the participants to the 150th Authority meeting of NPPA under DPCO, 2013.

1. Agenda item no. 1 - Confirmation of minutes of 149th Meeting held on 30.07.2026.

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 149th Meeting held on 30.07.2026.

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 13 (Thirteen) cases of retail price fixation of new drugs as presented in Agenda no. 4(1) to 4(13) falling under the purview of paragraph 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of 13 (Thirteen) 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 (₹)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	4(1)	Drotaverine Hydrochloride and Mefenamic Acid Tablets	Each film coated tablet contains: Drotaverine Hydrochloride IP 80 mg, Mefenamic Acid IP 250 mg	1 Tablet	M/s Innova Captab Ltd./ M/s Zorvia Healthcare Ltd.	14.59
2	4(2)	Empagliflozin, Linagliptin and Metformin Hydrochloride Extended-Release Tablets	Each film coated bilayer tablet contains: Empagliflozin 10 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Macleods Pharmaceuticals Ltd.	12.27
3	4(3)	Empagliflozin, Linagliptin and Metformin Hydrochloride Extended-Release Tablets	Each film coated bilayer tablet contains: Empagliflozin 25 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Macleods Pharmaceuticals Ltd.	14.33
4	4(4)	Escitalopram Oxalate and Clonazepam Mouth Dissolving Tablets	Each Mouth Dissolving tablet contains: Escitalopram Oxalate IP eq. to Escitalopram 10 mg, Clonazepam IP 0.5 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	15.69
5	4(5)	Glimepiride Tablets	Each uncoated tablet contains: Glimepiride IP 3 mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	12.48
6	4(6)	Glimepiride Tablets	Each uncoated tablet contains: Glimepiride IP 4 mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	13.47
7	4(7)	Telmisartan and Amlodipine Tablets	Each uncoated bilayered tablet contains: Telmisartan IP 40 mg, Amlodipine Besilate IP eq. Amlodipine 5 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Sun Pharmaceutical Industries Ltd.	13.08
8	4(8)	Telmisartan and Chlorthalidone Tablets	Each film coated tablet contains: Telmisartan IP 40 mg, Chlorthalidone IP 12.5 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Sun Pharmaceutical Industries Ltd.	13.27
9	4(9)	Thiocolchicoside, Aceclofenac & Paracetamol Tablets	Each film coated tablet contains: Thiocolchicoside IP 4 mg, Aceclofenac IP 100 mg, Paracetamol IP 325 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Seagull Pharmaceuticals Pvt. Ltd.	19.74
10	4(10)	Voglibose and Metformin Hydrochloride (SR) Tablets	Each uncoated bilayered tablet contains: Voglibose IP 0.3 mg, Metformin Hydrochloride IP 500 mg (as sustained release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Alkem Wellness Ltd.	13.55
11	4(11)	Dolutegravir, Lamivudine and Tenofovir Alafenamide Tablets	Each film coated tablet contains: Lamivudine IP 300 mg, Tenofovir Alafenamide Fumarate IP eq. to Tenofovir Alafenamide 25 mg,	1 Tablet	M/s Emcure Pharmaceuticals Ltd.	120.07

			Dolutegravir Sodium IP eq. to Dolutegravir 50 mg			
Without prior price approval case						
12	4(12)	Donepezil and Memantine Tablets	Each film coated tablet contains: Donepezil Hydrochloride 5mg Memantine Hydrochloride 10mg	1 Tablet	M/s Cipla Limited	12.31 (Note-1)
13	4(13)	Rabeprazole sodium and Domperidone Capsules	Each hard gelatin capsule contains: Rabeprazole Sodium IP 20 mg (As Enteric Coated Pellets), Domperidone IP 30mg (As Sustained Release Pellets)	1 Capsule	M/s. Ved Lifesavers (P) Ltd./ M/s German Remedies Pharmaceuticals Private Limited	7.47 (Note-1)

Note-1: The company had already launched the formulation without obtaining prior price approval from NPPA; therefore, the said retail price is applicable only to the individual manufacturer/marketer.

5. Agenda item no. 5: Minutes of 79th meeting of the Multidisciplinary Committee of Experts held on 27.07.2026.

5.1 Noted.

6. Agenda item no. 6: Application for extension of ceiling price of IV fluids with special features - under para 11(3) of DPCO, 2013 by M/s Silica Healthcare Pvt. Ltd. (Manufacturer & Marketer)

6.1 The Authority noted that M/s Silica Healthcare Pvt. Ltd. vide email dated 24.04.2026 applied for approval of prices of special features under Para-11(3) of DPCO, 2013 for IV Fluids packed in 'Non-glass Euro Head' and 'Non-glass Euro Head Dual Port' Bottles with special features for the following formulations:

S.No.	Product Name	Concentration / Volume	Packaging Type
1	Compound Sodium Lactate Injection IP	500 ml	Euro Head Dual Port
2	Compound Sodium Lactate Injection IP	500 ml	Euro Head
3	Metronidazole Injection IP	5 mg/ml (100 ml)	Euro Head Dual Port
4	Metronidazole Injection IP	5 mg/ml (100 ml)	Euro Head
5	Ciprofloxacin Injection IP	2 mg/ml (100 ml)	Euro Head Dual Port
6	Ciprofloxacin Injection IP	2 mg/ml (100 ml)	Euro Head
7	Mannitol Injection IP	20% w/v (100 ml)	Euro Head Dual Port
8	Mannitol Injection IP	20% w/v (100 ml)	Euro Head
9	Mannitol Injection IP	20% w/v (300 ml)	Euro Head

6.2 The Authority further noted that the matter was deliberated by the Multidisciplinary Committee (MDC) in its 77th meeting held on 15.05.2026, 78th meeting held on 24.06.2026 and 79th MDC meeting held on 27.07.2026 wherein the Committee examined the documents submitted by the company including flow rate analysis, certificate of analysis for plastic used in manufacturing of the plastic containers for the applied formulations. The Committee further noted that the products possess the features of self-sealability, self-collapsibility and Euro Head/Euro Head Dual Port to prevent contamination. The Committee also noted that the ceiling price for Mannitol Injection 20% has been notified on per ml basis and a separate ceiling price for the said formulation with special features has been notified on per ml basis for pack sizes of 100 ml and 350 ml. Since the company has applied for separate ceiling price for 300 ml pack

of Mannitol Injection 20% in addition to 100 ml pack, the Committee recommended the separate ceiling price for 300 pack on per ml basis.

6.3 The Authority deliberated upon the matter and approved the recommendation of the MDC to extend the applicable separate ceiling price to M/s Silica Healthcare Pvt. Ltd. under the provisions of Para 11(3) of DPCO, 2013 as below:

No.	Product Name	Concentration / Volume	Packaging Type	Ceiling Price (in ₹)	Notification details
1	Compound Sodium Lactate Injection IP	500 ml	Euro Head Dual Port	66.52 / each pack	1584(E) dated 25.03.2026
2	Compound Sodium Lactate Injection IP	500 ml	Euro Head		
3	Metronidazole Injection IP	5 mg/ml (100 ml)	Euro Head Dual Port	0.25 per ml	1586(E) dated 25.03.2026
4	Metronidazole Injection IP	5 mg/ml (100 ml)	Euro Head		
5	Ciprofloxacin Injection IP	2 mg/ml (100 ml)	Euro Head Dual Port	0.23 per ml	
6	Ciprofloxacin Injection IP	2 mg/ml (100 ml)	Euro Head		
7	Mannitol Injection IP	20% w/v (100 ml)	Euro Head Dual Port	0.41 per ml	
8	Mannitol Injection IP	20% w/v (100 ml)	Euro Head		
9	Mannitol Injection IP	20% w/v (300 ml)	Euro Head		

7. Agenda item no. 7: Application for extension of ceiling price of IV fluids with packaging in non-glass with special features - under para 11(3) of DPCO, 2013 by M/s Indbest Healthcare Pvt. Ltd. (Manufacturer & Marketer)

7.1 The Authority noted that M/s Indbest Healthcare Pvt. Ltd. vide email dated 09.06.2026 applied for approval of prices of special features under Para-11(3) of DPCO, 2013 for their IV fluids packaged in ISBM technology PP Bottles with dual port with special features for the following formulations:

No.	Product Name	Concentration / Volume	Packaging Type
1	Sodium Chloride Injection IP 0.9% w/v	100 ml	PP bottles- Dual Port cap
2	Sodium Chloride Injection IP 0.9% w/v	250 ml	PP bottles- Dual Port cap
3	Sodium Chloride Injection IP 0.9% w/v	500 ml	PP bottles- Dual Port cap

7.2 The Authority further noted that the matter was deliberated by the Multidisciplinary Committee (MDC) in its 78th meeting held on 24.06.2026 and 79th meeting held on 27.07.2026. The Committee examined the documents submitted by the company including flow rate analysis and certificate of analysis for plastic used in manufacturing of the plastic containers for the applied formulations. The Committee further noted that the products possess the features of self-sealability, self-collapsibility and dual port to prevent contamination. Accordingly, the Committee recommended the separate ceiling price for the applied formulations.

7.3 The Authority deliberated upon the matter and approved the recommendation of the MDC to extend the applicable separate ceiling price to M/s Indbest Healthcare Pvt. Ltd. under the provisions of Para 11(3) of DPCO, 2013 as below:

S. No.	Name of the Formulation	Pack size	Ceiling Price (in ₹)	Notification details
1	Sodium Chloride Injection IP 0.9% w/v	100 ml	43.07 / each pack	1583(E) dated 25.03.2026
2	Sodium Chloride Injection IP 0.9% w/v	250 ml	63.59 / each pack	
3	Sodium Chloride Injection IP 0.9% w/v	500 ml	90.05 / each pack	

8. Agenda item no. 8: Application for exemption of 'New Drug'- Povidone Iodine Throat Spray 0.45 % w/v under Paragraph 32(iii) of the Drugs (Prices Control) Order 2013

8.1 The Authority recalled that the matter had earlier been placed before it in its 144th meeting held on 24.03.2026, based on the recommendation of the MDC made during its 75th meeting held on 11.02.2026, 'to grant exemption under Para 32(iii) of DPCO, 2013 to M/s G.S. Pharmbutor Private Limited for "Povidone Iodine Throat Spray 0.45% w/v" for a period of five years from the date of its market approval in India'. The Authority deliberated upon the matter and deferred it for further examination in order to meet the requirement under Para 32(iii) of DPCO, 2013.

8.2 The Authority noted that the matter was considered in the 78th and 79th MDC meetings held on 24.06.2026 and 27.07.2026, respectively. The Committee observed that exemption under Para 32(iii) requires a new drug involving a new delivery system and indigenous R&D. While the company submitted CDSCO's new drug permission and demonstrated the product, it also claimed that the product was developed at a DSIR-approved laboratory. The Committee, therefore, sought specific evidence substantiating the company's claim of indigenous R&D.

In response, the company submitted documents including DSIR recognition, R&D infrastructure and development records, formulation and validation data, CDSCO approval with Phase III clinical trial data, and details of the R&D team. The Committee observed that the documents substantiated indigenous R&D at a DSIR-recognized facility and, accordingly, reiterated its recommendation to grant exemption under Para 32(iii) of DPCO, 2013 to M/s G.S. Pharmbutor Private Limited for "Povidone Iodine Throat Spray 0.45% w/v" for five years from the date of market approval in India.

8.3 The Authority deliberated upon the matter in detail and accepted the recommendation of the MDC to grant exemption to M/s G.S. Pharmbutor Private Limited for the formulation "Povidone Iodine Throat Spray 0.45% w/v" under Para 32(iii) of DPCO, 2013 for a period of five years w.e.f. 17.12.2024, being the date of grant of market approval by CDSCO.

9. Agenda item no. 9: Status of implementation of Review cases

9.1 Noted.

10. Agenda item no. 10: Revision of retail price of 'Each 5 ml contains: Paracetamol IP 250 mg + Phenylephrine Hydrochloride IP 5 mg + Chlorpheniramine Maleate IP 2 mg + Ammonium Chloride IP 120 mg + Sodium Citrate IP 60 mg + Menthol IP 1 mg Suspension' for M/s Windlas Biotech Ltd (Manufacturer) For M/s. Biological E. Ltd. (Marketer)' based on review order

10.1 The Authority deliberated upon the matter regarding review of the retail price of the formulation “*Each 5 ml contains: Paracetamol IP 250 mg + Phenylephrine Hydrochloride IP 5 mg + Chlorpheniramine Maleate IP 2 mg + Ammonium Chloride IP 120 mg + Sodium Citrate IP 60 mg + Menthol IP 1 mg Suspension*” for M/s Windlas Biotech Limited and M/s Biological E. Limited.

10.2 The Authority noted that the formulation had been launched by M/s Biological E. Limited in July 2023 without prior price approval and, accordingly, the retail price was initially fixed on the basis of the market data for December 2022, i.e. six months prior to the date of launch. Subsequently, pursuant to the review order dated 21.05.2026 issued by the Department of Pharmaceuticals, additional market data furnished by Pharmarack was considered and the retail price was reworked and uploaded on NPPA website. No representation has been received against the revised draft working sheet uploaded on 06.08.2026.

10.3 After detailed deliberations, the Authority approved the revised retail price of ₹0.70 per ml for the aforesaid formulation for M/s Windlas Biotech Limited and M/s Biological E. Limited, in supersession of the retail price of ₹0.41 per ml notified vide S.O. 3563(E) dated 01.08.2025.

11. Agenda item no. 11: Revision of the Internal Guidelines dated 07.10.2016 for Processing of Overcharging Cases under the Drugs (Prices Control) Order, 2013

11.1 The Authority noted the proposal on revision of internal guidelines issued on 07.10.2016 for processing of overcharging cases in light of the recent amendment of the DPCO, 2013. The draft guidelines were circulated and the members were requested to send their comments if any, within 10 working days. The guidelines will stand deemed to be adopted if no comments are received.

The Authority members placed on record their deep appreciation for the valuable contribution and exemplary leadership of the Chairman, Shri P. Krishnamurthy, during his tenure at the National Pharmaceutical Pricing Authority (NPPA). The members acknowledged his dedicated service and able leadership that have contributed significantly to the effective functioning of the Authority and furthering its mandate. The members expressed their sincere gratitude to the Chairman for his distinguished service and extended their best wishes on his superannuation.

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

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(Sai Ahlladini Panda)
Member Secretary