

मिसिलस.- 8(138)/2025/डी.पी/एनपीपीए-डीवी-II

F. No. 8(138)/2025/DP/NPPA-Div. II

कार्यवाहीस. : 270/138/2025/F

Proceeding No: 270/138/2025/F

Minutes of the 270th (overall) and 138th meeting of the Authority under DPCO, 2013 held on 30.10.2025 at 12:00 noon.

The 270th meeting of the Authority (overall), which is the 138th meeting under the DPCO, 2013 was held on 30th October, 2025 at 12:00 noon 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 Manmohan Sachdeva, Additional Chief Adviser Cost (ACAC), 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, Advisor (Cost)
- (ii) Shri Kumar Aman Bharti, Director (Monitoring)
- (iii) Shri Mahaveer Saini, Deputy Director (Pricing)
- (iv) Ms. Yuvika Panwar, Assistant Director (Pricing)
- (v) Shri Bhiva Ram Yadav, Assistant Director (Pricing)
- (vi) Shri Mayur Panwar, Assistant Director (Pricing)

1. Agenda item no. 1 - Confirmation of minutes of the 137th meeting held on 15.09.2025.

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

2. Agenda item no. 2 - (a) Action Taken Report on decisions taken by NPPA in its 137th meeting held on 15.09.2025.

2.1 Noted.

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

3.1 Noted.

4. Agenda item no. 4 – New drug applications for price fixation under paragraph 5 and 15 of DPCO, 2013.

4.1 The Authority deliberated on 28 (Twenty-Eight) cases of retail price fixation of new drugs as presented in Agenda no. 4 (1) to 4 (28) falling under the purview of paragraph 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of 28 (Twenty-Eight) new drugs under paragraph 5 and 15 of the DPCO 2013 as given in **Table 1 below:**

Table No. 1: Retail price fixation of new drugs

Sl. No . (1)	Name of the Formulation / Brand Name (2)	Strength (3)	Unit (4)	Manufacturer & Marketing Company (5)	Retail Price (Rs.) (6)
1	Amlodipine & Valsartan Tablets	Each film coated tablet contains: Amlodipine besylate IP eq. to Amlodipine 5 mg Valsartan IP 80 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Alembic Pharmaceuticals Ltd.	7.41
2	Dapagliflozin, Sitagliptin & Metformin Hydrochloride (Extended Release) Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP Eq. to Dapagliflozin 10 mg Sitagliptin Phosphate Monohydrate IP Eq. to Sitagliptin 100 mg Metformin Hydrochloride IP 500 mg (As extended-release form)	1 Tablet	M/s Windlas Biotech Ltd. / M/s Jagsonpal Pharmaceuticals Ltd.	18.18
3	Empagliflozin, Linagliptin & Metformin Hydrochloride Extended Release Tablets	Each film coated bilayer tablet contains: Empagliflozin 10mg Linagliptin 5 mg Metformin Hydrochloride (Extended Release) IP 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Corona Remedies Pvt. Ltd.	29.21
4	Empagliflozin, Sitagliptin and 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 Alembic Pharmaceuticals Ltd.	25.00

Sl. No	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
5	Levocetirizine Hydrochloride & Montelukast Syrup	Each 5 ml contains: Levocetirizine Hydrochloride IP 2.5 mg Montelukast Sodium IP eq. to Montelukast 5 mg	1 ml	M/s Ravenbhel Healthcare Pvt. Ltd. M/s Cipla Ltd.	1.88
6	Linagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayered tablet contains: Linagliptin 5 mg Metformin Hydrochloride IP 500 mg (As extended-release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s Primus Remedies Pvt. Ltd.	10.09
7	Metoprolol succinate Extended Release, Amlodipine & Telmisartan Tablets	Each film coated bilayered tablet contains: Metoprolol succinate IP 23.75 mg eq. to Metoprolol Tartrate 25 mg (As extended release) Amlodipine Besilate IP eq to Amlodipine 5 mg Telmisartan IP 40 mg	1 Tablet	M/s Ajanta Pharma Ltd./ M/s Sun Pharma Laboratories Ltd.	13.01
8	Mefenamic acid & Paracetamol Tablets	Each uncoated tablet contains: Mefenamic Acid IP 500 mg Paracetamol IP 325 mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd./ M/s Dr. Reddy's Laboratories Ltd.	3.91
9	S (-) Pantoprazole for Injection (Lyophilized)	Each vial contains: S (-) Pantoprazole Sodium equivalent to S (-) Pantoprazole 20mg	1 Vial	M/s Gufic Biosciences Ltd.	118.39
10	S (-) Pantoprazole for Injection (Lyophilized)	Each vial contains: S (-) Pantoprazole Sodium equivalent to S (-) Pantoprazole 20mg	1 Vial	M/s Gufic Biosciences Ltd./ M/s Tyykem Pvt. Ltd.	118.39
11	Paracetamol & Caffeine Tablets	Each uncoated tablet contains: Paracetamol IP 650 mg Caffeine IP 50 mg	1 Tablet	M/s Psychotropics India Ltd.	4.01
12	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50 mg, Glimepiride IP 1 mg, Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Ipca Laboratories Ltd.	11.18
13	Sitagliptin, Glimepiride &	Each film coated tablet contains:	1 Tablet	M/s Exemed Pharmaceuticals/	12.78

Sl. No	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	Metformin Hydrochloride Tablets	Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50 mg, Glimepiride IP 2 mg, Metformin Hydrochloride IP 1000 mg		M/s Ipca Laboratories Ltd.	
14	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50 mg, Glimepiride IP 1 mg, Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Ipca Laboratories Ltd.	13.24
15	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP equivalent to Sitagliptin 50 mg, Glimepiride IP 2 mg, Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Ipca Laboratories Ltd.	14.92
16	Alginate Raft-forming Oral Suspension BP	Each 5ml contains: Sodium Alginate IP 250 mg Sodium Bicarbonate IP 133.5 mg Calcium Carbonate IP 80 mg	1 ml	M/s Skymap Pharmaceuticals Pvt. Ltd. M/s German Remedies Pharmaceuticals Pvt. Ltd.	0.95
17	Telmisartan & Amlodipine Tablets	Each uncoated bilayered tablet contains: Telmisartan IP 40 mg Amlodipine Besilate IP 5 mg	1 Tablet	M/s Swiss Garnier Life Sciences/ M/s SRK Puremed LLP	7.14
18	Telmisartan & Amlodipine Tablets	Each uncoated bilayered tablet contains: Telmisartan IP 80 mg Amlodipine Besilate Equivalent to Amlodipine IP 5 mg	1 Tablet	M/s Swiss Garnier Life Sciences/ M/s SRK Puremed LLP	9.82
19	Telmisartan & Chlorthalidone Tablets	Each uncoated tablet contains: Telmisartan IP 40 mg Chlorthalidone IP 12.5 mg	1 Tablet	M/s Swiss Garnier Life Sciences/ M/s SRK Puremed LLP	8.93
20	Telmisartan & Chlorthalidone Tablets	Each uncoated tablet contains: Telmisartan IP 80 mg	1 Tablet	M/s Swiss Garnier Life Sciences/ M/s SRK Puremed LLP	11.16

Sl. No	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
		Chlorthalidone IP 12.5 mg			
21	Telmisartan, Cilnidipine and Metoprolol Succinate (ER) Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Metoprolol Succinate IP 23.75 mg eq. to Metoprolol Tartrate (As extended release) 25 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Aristo Pharmaceuticals Pvt. Ltd.	11.39
22	Telmisartan, Cilnidipine and Metoprolol Succinate (ER) Tablets	Each film coated bilayered tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Metoprolol Succinate IP 47.50 mg eq. to Metoprolol Tartrate (As extended release) 50 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s Aristo Pharmaceuticals Pvt. Ltd.	14.35
23	Telmisartan & Hydrochlorothiazide Tablets	Each uncoated tablet contains: Telmisartan IP 80 mg Hydrochlorothiazide IP 12.5 mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	14.00
24	Telmisartan & Hydrochlorothiazide Tablets	Each uncoated bilayered tablet contains: Telmisartan IP 80 mg Hydrochlorothiazide IP 12.5 mg	1 Tablet	M/s Swiss Garnier Life Sciences/ M/s SRK Puremed LLP	10.29
25	Theophylline Anhydrous (SR) & Montelukast Sodium Tablets	Each Film coated Tablet Contains: Theophylline (Anhydrous) IP 400 mg (as sustained release) Montelukast Sodium IP Equivalent to Montelukast 10 mg	1 Tablet	Ms East African (I) Overseas/ M/s Zydus Healthcare Ltd.	13.78
26	Amoxycillin & Potassium Clavulanate tablets	Each film coated tablet contains: Amoxycillin Trihydrate IP Equivalent to Amoxycillin 875 mg Potassium Clavulanate Diluted IP Equivalent to Clavulanic Acid 125 mg	1 Tablet	M/s Alps Communication Pvt. Ltd./ M/s Indoco Remedies Ltd.	42.84
27	Teneligliptin, Dapagliflozin, Metformin	Each film-coated bilayer tablet contains: Teneligliptin Hydrobromide	1 Tablet	M/s Synokem Lifesciences Pvt. Ltd /	13.39

Sl. No	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	(Sustained Release) Tablets	Hydrate IP eq. to Teneiglipitin 20 mg, Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10 mg, Metformin Hydrochloride I.P 1000 mg (As Sustained Release)		M/s Glenmark Pharmaceuticals Ltd.	
28	Povidone Iodine alcoholic prep solution 10% w/v	Povidone Iodine IP 10.0% w/v (available Iodine 1.0% w/v) Ethanol IP 30% v/v	1 ml	M/s G.S. Pharmbutor Pvt. Ltd./ M/s Win-Medicare Pvt. Ltd.	1.14

5. Agenda item no. 5: Fixation of ceiling prices of 6 scheduled formulations under revised Schedule I (NLEM, 2022).

5.1 The Authority noted that the draft working sheets for 6 formulations were uploaded on NPPA website on 18.09.2025 for 10 working days based on October 2023 data and database for the month of October 2023. Hence, the effect of change in WPI for 2024 @ (+) 0.00551% (effective from 01.04.2024) and WPI for 2025 @ (+) 1.74028% (effective from 01.04.2025) have also been considered in the draft work sheets.

5.2 The Authority noted that representation has been received in respect of four formulations.

- (i) M/s Stedman Pharmaceuticals Pvt. Ltd. represented that it's PTR of ₹0.34/ml for Ethyl Alcohol (Denatured) Solution 70% as considered in draft worksheet is incorrect and the same may be considered in line with latest form V submitted by the company on 28.01.2025 at ₹0.42/ml. The Authority noted that the PTR ₹0.42/ml as claimed by M/s Stedman Pharmaceuticals Pvt. in Form V filed on 28.01.2025 is effective from May, 2024. The company did not file Form V or Form II before this date. Since, the revision in PTR is considered only for the cases where Form II/V is filed within the timelines mentioned in Para 16 of DPCO 2013, the company's representation was not considered.
- (ii) M/s Zydus Lifesciences Limited for Ethyl alcohol (Denatured) Solution 70% stated that the price increase in last 12 years is only 10.2% and refixation with 26% reduction under NLEM 2022 may destabilize the availability and accessibility of the sanitizers. The representation was examined and not found tenable as draft working sheet was in compliance with provisions of DPCO, 2013.
- (iii) M/s Zydus Healthcare Limited also filed representation against "Human Normal Immunoglobulin Solution for infusion 5%, 10% and 16.5%", giving reference to pending court cases and that price fixation under NLEM, 2022 may trigger non-

availability of the formulation. The company also stated that WPI increase over existing ceiling price would ensure reasonable and transparent ceiling price. The representation received from M/s Zydus was examined and not found tenable as revision of ceiling price is done as per the provisions of DPCO, 2013. Further, the court cases mentioned by the company relate to another formulation and do not have any implication on the ceiling price fixation under NLEM 2022.

- (iv) The Authority also noted that M/S Zydus had mentioned that ceiling price of 16.5% immunoglobulin fixed under NLEM 2015 is sub-judice. The Authority noted that although the matter is sub-judice, no stay has been imposed for implementation of ceiling price. Accordingly, the ceiling price as fixed under NLEM 2015 and as revised based on WPI from year to year are effective. Hence, the representation was not found tenable.

5.3 Accordingly, the Authority deliberated upon the matter and approved the ceiling prices of following six scheduled formulations:

Table 2: Revised ceiling prices of 6 formulations under NLEM, 2022

S.No.	Medicines	Dosage form(s) and strength(s)	Prevailing ceiling price (in Rs.)	Ceiling price under NLEM, 2022 (in Rs.)	Unit
1	Riboflavin	Tablet 10mg	-	1.11	1 Tablet
2	Peritoneal dialysis solution	As licensed	-	0.22	1 ML
3	Ethyl alcohol (Denatured)	Solution 70%	0.54	0.40	1 ML
4	Human normal immunoglobulin	Solution for infusion (16.5%)	503.13	478.57	1 ML
5	Human normal immunoglobulin	Solution for infusion (10%)	264.57	206.53	1 ML
6	Human normal immunoglobulin	Solution for infusion (5%)	195.41	148.60	1 ML

6. Agenda item no. 6: Minutes of 71st meeting of Multidisciplinary Committee of Experts held on 16.09.2025 and 72nd MDC meeting held on 09.10.2025.

6.1 Noted.

7. Agenda item no. 7: Application for approval of separate ceiling prices under Para 11(3) of the DPCO, 2013 for IV fluid in Euro Head / PP Bottles with special features by M/s IV Tech Healthcare.

7.1 The Authority noted that M/s IV Tech Healthcare vide email dated 18.07.2025 applied for extension of separate ceiling price under Para 11(3) for following

I.V. fluids stating that their IV fluids packaged in Twin port Euro Head / PP bottles, which incorporate special features enhancing their utility and performance:

S. No.	Name of Product	Pack Size	Notification	Claimed MRP ex. GST
1.	Metronidazole Injection: Each 100ml contains Metronidazole 0.5gm	100ml	1486(E) dt. 27.03.25	25.00
2.	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	500ml	1485(E) dt. 27.03.25	83.70
3.	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	1000ml	1485(E) dt. 27.03.25	96.77
4.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml	1485(E) dt. 27.03.25	87.01
5.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	1000ml	1485(E) dt. 27.03.25	101.68
6.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	100ml	1485(E) dt. 27.03.25	42.79
7.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml	1485(E) dt. 27.03.25	89.47
8.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	1000ml	1485(E) dt. 27.03.25	100.22
9.	Compound Sodium Lactate Injection	500ml	1474(E) dt. 27.03.25	66.09
10.	Compound Sodium Lactate Injection	1000ml	1474(E) dt. 27.03.25	116.20
11.	Mannitol Injection 20%: Each 100ml contains Mannitol IP 20gm	100ml	1486(E) dt. 27.03.25	41.00
12.	Dextrose Injection IP 25%: Each 100ml contains Dextrose anhydrous IP 25gm	100ml	1486(E) dt. 27.03.25	24.00

7.2 The Authority noted that the matter was deliberated by the MDC in its 70th meeting held on 05.08.2025 and 71st meeting held on 16.09.2025, wherein the company demonstrated its products. The Committee examined the documents relating to flow rate analysis, certificate of analysis for plastic used in manufacturing of the plastic containers for the applied formulations. The Committee noted that the product bears the features of self-sealability, self-collapsibility and has a twin port Euro head to prevent the contamination. Accordingly, the Committee recommended the separate ceiling price for 12 formulations.

7.3 The Authority deliberated upon the matter and approved the recommendation of the MDC to extend the present applicable separate ceiling price to M/s IV Tech Healthcare under the provision of Para 11 (3) of DPCO 2013 as below-

S. No.	Name of Product	Pack Size	Notification	Separate Ceiling price ex. GST
1.	Metronidazole Injection: Each 100ml contains Metronidazole 0.5gm	100ml	1486(E) dt. 27.03.25	0.25/ml
2.	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	500ml	1485(E) dt. 27.03.25	83.70/pack
3.	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	1000ml	1485(E) dt. 27.03.25	96.77/pack
4.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml	1485(E) dt. 27.03.25	87.01/pack
5.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	1000ml	1485(E) dt. 27.03.25	101.68/pack
6.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	100ml	1485(E) dt. 27.03.25	42.79/pack
7.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml	1485(E) dt. 27.03.25	89.47/Pack
8.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	1000ml	1485(E) dt. 27.03.25	100.22/Pack
9.	Compound Sodium Lactate Injection	500ml	1474(E) dt. 27.03.25	66.09/Pack
10.	Compound Sodium Lactate Injection	1000ml	1474(E) dt. 27.03.25	116.20/Pack
11.	Mannitol Injection 20%: Each 100ml contains Mannitol IP 20gm	100ml	1486(E) dt. 27.03.25	0.41/ml
12.	Dextrose Injection IP 25%: Each 100ml contains Dextrose anhydrous IP 25gm	100ml	1486(E) dt. 27.03.25	0.24/ml

8. Agenda item no. 8: Application for approval of company for scheduled drugs under special features (Euro Head) by M/s Safal Lifescience Private Limited (Manufacturer) and M/s One Drip Healthcare Private Limited (Marketer).

8.1 The Authority noted that M/s Safal Lifescience Private Limited vide letter dated 17.06.2025 (complete application on 20.08.2025) applied for separate ceiling prices under

Para 11(3) of the DPCO, 2013 with M/s One Drip Healthcare Private Limited as marketer, for the following formulations:

Sr. No.	Name of Product	Pack Size	Brand Name
1.	Dextrose Injection IP 5% w/v - 500ml LDPE Bottle with EURO Head	500ml	DRIPEURO
2.	Sodium Chloride Injection IP 0.9% w/v - 100ml LDPE Bottle with EURO Head	100ml	DRIPEURO
3.	Sodium Chloride Injection IP 0.9% w/v - 500ml LDPE Bottle with EURO Head	500ml	DRIPEURO
4.	Dextrose 5% w/v + Sodium Chloride 0.9% w/v Injection IP - 500ml LDPE Bottle with EURO Head	500ml	DRIPEURO
5.	Compound Sodium Lactate Injection IP - 500ml LDPE Bottle with EURO Head	500ml	DRIPEURO

8.2 The Authority noted that the matter was deliberated by the MDC in its 71st meeting held on 16.09.2025 and 72nd meeting held on 09.10.2025, wherein the company demonstrated its products. The Committee examined the documents relating to flow rate analysis, certificate of analysis for plastic used in manufacturing of the plastic containers for the applied formulations. The Committee noted that the product bears the features of self-sealability, self-collapsibility and has a dual port to prevent the contamination. Accordingly, the Committee recommended the separate ceiling price for the 5 formulations for M/s Safal Lifescience Private Limited (Manufacturer) and M/s One Drip Healthcare Private Limited (Marketer)

8.3 The Authority deliberated upon the matter and approved the recommendation of the MDC to extend the present applicable separate ceiling price to M/s Safal Lifescience Private Limited (Manufacturer) and M/s One Drip Healthcare Private Limited (Marketer) under the provision of Para 11 (3) of DPCO 2013 as below-

S. No.	Name of Product	Pack Size	Applicable ceiling price w.e.f. 01.04.2025 (S.O. No. & Date)
1.	Dextrose Injection IP 5% w/v	500ml	83.70/pack (1485(E) dt.27.03.2025)
2.	Sodium Chloride Inj 0.9% w/v	100ml	42.79/pack (1485(E) dt.27.03.2025)
3.	Sodium Chloride Inj 0.9% w/v	500ml	89.47/pack (1485(E) dt.27.03.2025)
4.	Dextrose 5% + Sodium Chloride 0.9% Inj.	500ml	87.01/pack (1485(E) dt.27.03.2025)
5.	Compound Sodium Lactate Injection	500ml	66.09/pack (1474(E) dt.27.03.2025)

9. Agenda item no. 9: Application for approval of separate ceiling prices under Para 11(3) of the DPCO, 2013 for Dual Port Bottles of Large Volume Parenteral by M/s Life Infusion Pharmaceuticals Pvt. Ltd.

9.1 The Authority noted that M/s Life Infusion Pharmaceuticals Pvt. Ltd. vide letter dated 29.07.2025 applied for separate ceiling prices under Para 11(3) of the DPCO, 2013 for LVP products with special features with dual port in plastic collapsible bottles through ISBM technology for the following IV Fluids:

S. No.	Name of Product	Pack Size
1	Metronidazole Injection: Each 100ml contains Metronidazole 0.5gm	100ml
2	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	500ml
3	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	1000ml
4	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml
5	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	1000ml
6	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	100ml
7	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml
8	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	1000ml
9	Compound Sodium Lactate Injection	500ml
10	Compound Sodium Lactate Injection	1000ml
11	Mannitol Injection 20%: Each 100ml contains Mannitol IP 20gm	100ml
12	Dextrose Injection IP 25%: Each 100ml contains Dextrose anhydrous IP 25gm	100ml
13.	Ciprofloxacin Injection IP (0.2% w/v)	100ml

9.2 The Authority noted that the matter was deliberated by the MDC in its 71st meeting held on 16.09.2025 and 72nd meeting held on 09.10.2025, wherein the company demonstrated its products. The Committee examined the documents relating to flow rate analysis, certificate of analysis for plastic used in manufacturing of the plastic containers for the applied formulations. The Committee noted that the product has the features of self-sealability, self-collapsibility and has a twin port to prevent the contamination. Accordingly, the Committee recommended the separate ceiling price for 13 formulations.

9.3 The Authority deliberated upon the matter and approved the recommendation of the MDC to extend the present applicable separate ceiling price to M/s Life Infusion Pharmaceuticals Pvt. Ltd under the provision of Para 11 (3) of DPCO 2013 as below-

S. No.	Name of Product	Pack Size	Applicable ceiling price w.e.f. 01.04.2025 (S.O. No. & Date)
1.	Metronidazole Injection: Each 100ml contains Metronidazole 0.5gm	100ml	0.25/ml (1486(E) dt. 27.03.25)
2.	Dextrose Injection IP 5% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm	500ml	83.70/pack (1485(E) dt. 27.03.25)
3.	Dextrose Injection IP 5% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm	1000ml	96.77/pack (1485(E) dt. 27.03.25)
4.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml	87.01/pack (1485(E) dt. 27.03.25)
5.	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	1000ml	101.68/pack (1485(E) dt. 27.03.25)
6.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	100ml	42.79/pack (1485(E) dt. 27.03.25)
7.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml	89.47/pack (1485(E) dt. 27.03.25)
8.	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	1000ml	100.22/pack (1485(E) dt. 27.03.25)
9.	Compound Sodium Lactate Injection	500ml	66.09/pack (1474(E) dt. 27.03.25)
10.	Compound Sodium Lactate Injection	1000ml	116.20/pack (1474(E) dt. 27.03.25)
11.	Mannitol Injection 20%: Each 100ml contains Mannitol IP 20gm	100ml	0.41/ml (1486(E) dt. 27.03.25)
12.	Dextrose Injection IP 25%: Each 100ml contains Dextrose anhydrous IP 25gm	100ml	0.24/ml (1486(E) dt. 27.03.25)
13.	Ciprofloxacin Injection IP (0.2% w/v)	100ml	0.23/ml (1486(E) dt. 27.03.25)

10. Agenda item no. 10: Application for separate ceiling price for IV fluids in special features under the provisions of Para 11 of the DPCO, 2013 by M/s Virchow Biotech Private Limited.

10.1 The Authority noted that M/s Virchow Biotech Private Limited vide email dated 10.09.2025 applied for extension of separate ceiling prices (as notified vide Notification No. 1474(E) & 1485(E) all dated 27.03.2025) under Para 11(3) of the DPCO, 2013 to its following IV fluids packaged in **Euro Head LVP bags**, which incorporate special features

viz. (i) self-collapsibility and self-sealability, (ii) not having air-vent, (iii) having no chance of contamination during manufacture / infusion / admixing level.

Sr. No.	Name of Product	Pack Size	Notification	Claimed MRP ex. GST
1	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	100ml	1485(E) dt. 27.03.25	42.79
2	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	250ml	1485(E) dt. 27.03.25	63.18
3	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml	1485(E) dt. 27.03.25	89.47
4	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	1000ml	1485(E) dt. 27.03.25	100.22
5	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	500ml	1485(E) dt. 27.03.25	83.70
6	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	1000ml	1485(E) dt. 27.03.25	96.77
7	Compound Sodium Lactate Injection	500ml	1474(E) dt. 27.03.25	66.09
8	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml	1485(E) dt. 27.03.25	87.01
9	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	250ml	Not fixed for special packaging	34.00
10	Dextrose Injection IP 10% w/v : Each 100ml contains Dextrose Anhydrous IP 10gm	500ml	Not fixed for special packaging	42.00
11	Dextrose Injection IP 10% w/v : Each 100ml contains Dextrose Anhydrous IP 10gm	1000ml	Not fixed for special packaging	39.00
12	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	250ml	Not fixed for special packaging	34.00

10.2 The Authority noted that the matter was placed before the Multidisciplinary Committee (MDC) in its 71st meeting held on 16.09.2025 and 72nd meeting held on 09.10.2025, wherein the company demonstrated its products as packed in Euro Head LVP bags. The Authority also noted that the applicant requested the Committee to allow him to withdraw the application for four formulations listed at S. No. 9 to 12 of above table. The same was agreed by the Committee.

10.2 The Committee examined the documents relating to flow rate analysis, certificate of analysis for plastic used in manufacturing of the LVP bags for the applied formulations. The Committee noted that the product i.e. LVP bags containing the respective products bear the features of self-sealability, self-collapsibility and have dual ports to prevent the

contamination. The Committee recommended separate ceiling price in respect of eight formulations mentioned from Sr. No. 1 to 8 of the above.

10.3 Accordingly, the Authority deliberated upon the matter and approved the recommendation of the MDC to extend the present applicable separate ceiling price to M/s Virchow Biotech Private Limited under the provision of Para 11 (3) of DPCO 2013 for the eight formulations as below-

S. No.	Name of Product	Pack Size	Applicable ceiling price w.e.f. 01.04.2025 (S.O. No. & Date)
1	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	100ml	42.79 (1485(E) dt. 27.03.25)
2	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	250ml	63.18 (1485(E) dt. 27.03.25)
3	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml	89.47 (1485(E) dt. 27.03.25)
4	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	1000ml	100.22 (1485(E) dt. 27.03.25)
5	Dextrose Injection IP 5% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm	500ml	83.70 (1485(E) dt. 27.03.25)
6	Dextrose Injection IP 5% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm	1000ml	96.77 (1485(E) dt. 27.03.25)
7	Compound Sodium Lactate Injection	500ml	66.09 (1474(E) dt. 27.03.25)
8	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml	87.01 (1485(E) dt. 27.03.25)

11. Agenda item no. 11: Application for extension of separate ceiling prices under Para 11(3) of the DPCO, 2013 for IV fluid in Euro Head with packaging in non-glass with special feature by M/s Klokter Life Sciences Pvt. Ltd. (Manufacturer) and Zee Laboratories Limited (Marketer).

11.1 The Authority noted that M/s Klokter Life Sciences Pvt. Ltd. vide email dated 09.09.2025 applied for extension of separate ceiling prices under Para 11(3) of the DPCO, 2013 stating that the following IV fluids (Notification No. 1474(E) & 1485(E) dated 27.03.2025) packaged in Euro Head bottles, which incorporate special features viz. (i) self-collapsibility and self-sealability, (ii) not having air-vent, (iii) having no chance of contamination during manufacture / infusion / admixing level.

Sr. No.	Name of Product	Pack Size	Notification
1	Dextrose Injection IP 5% w/v : Each 100ml contains Dextrose Anhydrous IP 5gm	500ml	1485(E) dt. 27.03.25

2	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml	1485(E) dt. 27.03.25
3	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml	1485(E) dt. 27.03.25
4	Compound Sodium Lactate Injection	500ml	1474(E) dt. 27.03.25

11.2 The Authority noted that the matter was placed before the Multidisciplinary Committee (MDC) in its 71st meeting held on 16.09.2025 and 72nd meeting held on 09.10.2025, wherein the company demonstrated its products. The Committee examined the documents relating to flow rate analysis, certificate of analysis for plastic used in manufacturing of the plastic containers for the applied formulations. Accordingly, the Committee recommended the separate ceiling price for M/s Klokter Life Sciences Pvt. Ltd. (manufacturer) and Zee Laboratories Limited (marketer) for 4 following formulations

11.3 The Authority deliberated upon the matter and approved the recommendation of the MDC to extend the present applicable separate ceiling price to M/s Klokter Life Sciences Pvt. Ltd. (manufacturer) and Zee Laboratories Limited (marketer) under the provision of Para 11 (3) of DPCO 2013 as below-

S. No.	Name of Product	Pack Size	Applicable ceiling price w.e.f. 01.04.2025 (S.O. No. & Date)
1	Dextrose Injection IP 5% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm	500ml	83.70/pack (1485(E) dt. 27.03.25)
2	Dextrose Injection IP 5% w/v & Sodium Chloride 0.9% w/v: Each 100ml contains Dextrose Anhydrous IP 5gm & Sodium Chloride IP 900mg	500ml	87.01/pack (1485(E) dt. 27.03.25)
3	Sodium Chloride 0.9% w/v: Each 100ml contains: Sodium Chloride IP 0.9gm	500ml	89.47/Pack (1485(E) dt. 27.03.25)
4	Compound Sodium Lactate Injection	500ml	66.09/Pack (1474(E) dt. 27.03.25)

12. Agenda item no. 12: Form-IV intimation by M/s GlaxoSmithKline Pharmaceutical Limited (GSK) for discontinuation of the scheduled formulation viz., Grisovin FP 250mg Tablet containing Griseofulvin under para 21(2) of DPCO, 2013

12.1 The Authority deliberated upon the matter in detail and noted that M/s GlaxoSmithKline Pharmaceuticals Ltd. had requested for discontinuation of their scheduled formulation "Grisovin FP 250mg" containing "Griseofulvin" in January, 2021 due to the closure of its overseas API supplier. The matter was examined in the Standing Committees meetings constituted to discuss discontinuation cases. Based on the

recommendation of the Committee direction was issued to the company to continue production for one year under para 21(2) of DPCO,2013 i.e., up to July, 2022 and identify an alternative API source and later directed to expedite the resumption of supplies after seeking an extended timeline. Based on the recommendation of the Standing Committee, directions were issued by the Authority under Para 3 of DPCO,2013 from time to time and currently the same is in force till 31.05.2026.

12.2 The Authority further noted that the company vide its letter dated 24.07.2025 requested for revocation of direction issued under Para-3 of DPCO, 2013 on the grounds of a major fire at its Indian contract manufacturing site, market shift toward Terbinafine and Itraconazole, a sharp decline in demand for the 250 mg tablet etc.

12.3 The Authority deliberated upon the matter in detail and noted that M/s GlaxoSmithKline Pharmaceuticals Limited (GSK) has a market share of 0.02% along with the sufficient number of market players for the subject scheduled formulation based on the July, 2025 market-based data. It was further observed that no complaints regarding shortages have been reported since 2021. In view of the above, the Authority after detailed deliberation, decided to revoke the directions issued under Paragraph 3 of the DPCO, 2013.

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


(Sai Ahlladini Panda)
Member Secretary