

मिसिलस.- 8(133)/2025/डी.पी/एनपीपीए-डीवी-II

F. No. 8(133)/2025/DP/NPPA-Div. II

कार्यवाहीस. : 265/133/2025/F

Proceeding No: 265/133/2025/F

Minutes of the 265th (overall) and 133rd meeting of the Authority under DPCO, 2013 held on 29.05.2025 at 03.30 p.m.

The 265th meeting of the Authority (overall), which is the 133rd meeting under the DPCO, 2013 was held on 29th May, 2025 at 03.30 p.m. under the Chairmanship of Shri P. Krishnamurthy, Chairman, NPPA. The following Authority members were present during the meeting:

- (i) Shri Manmohan Sachdeva, Additional Chief Adviser Cost (ACAC), O/o Chief Adviser (Cost), Department of Expenditure
- (ii) 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 Sanjay Kumar, Advisor (Cost)
- (ii) Shri Mahaveer Saini, Deputy Director (Pricing)
- (iii) Ms. Yuvika Panwar, Assistant Director (Pricing)

1. Agenda item no. 1 - Confirmation of Minutes of the 132nd Meeting held on 29.04.2025.

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

2. Agenda item no. 2 - (a) Action Taken Report (ATR) on decisions taken by NPPA in its 132nd Meeting held on 29.04.2025.

2.1 Noted.

3. Agenda item no. 3 - Status of New Drug applications

3.1 Noted.

Li mri

4. Agenda item no. 4 – New Drug applications for Price fixation under Para 5 and Para 15 of DPCO, 2013

4.1 The Authority deliberated on 41 (Forty-one) cases of retail price fixation of new drugs as presented in Agenda no. 4 (1) to 4 (41) falling under the purview of Para 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of 41 (Forty-one) new drugs under Para 5 and 15 of the DPCO 2013 as given in **Table 1** below-

Table No. 1: Retail price fixation of new drugs

Sl. No	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
1	Alginate Raft-Forming Oral Suspension	Each 5 ml contains: Sodium Alginate IP 250 mg Sodium Bicarbonate IP 133.5 mg Calcium Carbonate IP 80 mg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Apex Laboratories Pvt. Ltd.	0.93
2	Atorvastatin & Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP equivalent to Atorvastatin 10mg Ezetimibe IP 10mg	1 Tablet	M/s Safetab Life Science/ M/s Ajanta Pharma Ltd.	19.66
3	Atorvastatin & Ezetimibe Tablets	Each film coated tablet contains: Atorvastatin Calcium IP equivalent to Atorvastatin 80 mg Ezetimibe IP 10mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Zydus Healthcare Ltd.	54.29
4	Ceftriaxone, Sulbactam & Disodium Edetate Powder for solution for Infusion	Each vial contains: Ceftriaxone Sodium IP eq. to Ceftriaxone 1000 mg Disodium Edetate IP 37 mg Sulbactam Sodium IP eq. Sulbactam 500 mg	1 vial	M/s BDR Pharmaceuticals International Pvt. Ltd./ M/S Glenmark Pharmaceuticals Ltd.	515.57
5	Cefuroxime & Potassium Clavulanate Tablets	Each film coated tablet contains: Cefuroxime Axetil IP eq. to Cefuroxime 500 mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125 mg	1 Tablet	M/s Supermax Drugs & Pharmaceuticals Pvt. Ltd. / M/s Profic Organic Ltd.	60.62
6	Cholecalciferol Oral Drops	Each ml of Suspension contains: Vitamin D3 IP 800 IU	1 ml	M/s Stedman Pharmaceuticals Pvt. Ltd.	4.76
7	Clindamycin & Nicotinamide gel	Clindamycin Phosphate IP eq. to Clindamycin 1.00% w/w Nicotinamide IP 4.00% w/w	1 gm	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	7.24
8	Iron, Folic Acid & Cyanocobalamin Syrup	Each 5 ml contains: Ferric Ammonium Citrate IP 110 mg Folic Acid IP 1.5 mg Cyanocobalamin IP 15 mcg Sorbitol (70%) (Non-Crystallising)	1 ml	M/s East African (I) Overseas / M/s Mankind Prime Labs Pvt. Ltd.	0.23

Sl. No	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
9	Melatonin & Zolpidem Tartrate Tablets	Each film coated tablet contains: Melatonin BP 3 mg Zolpidem Tartrate IP 5 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Ipca Laboratories Ltd.	6.62
10	Melatonin & Zolpidem Tartrate Tablets	Each film coated tablet contains: Melatonin BP 3 mg Zolpidem Tartrate IP 10 mg	1 Tablet	M/s Windlas Biotech Ltd./ M/s Ipca Laboratories Ltd.	8.73
11	Polmacoxib & Paracetamol Tablets	Each uncoated tablet contains: Polmacoxib IH 2 mg Paracetamol IP 325 mg	1 Tablet	M/s Hetero Labs Ltd. M/s Zuventus Healthcare Ltd.	15.39
12	Empagliflozin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayered tablet contains: Empagliflozin 10mg Metformin Hydrochloride 1000mg (as extended release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Blue Cross Laboratories Pvt. Ltd.	9.90
13	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	18.10
14	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Zydus Healthcare Ltd.	18.10
15	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Unison Pharmaceuticals Pvt. Ltd.	19.01
16	Empagliflozin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg (as Extended release)	1 Tablet	M/s MSN Laboratories Pvt. Ltd.	17.86
17	Empagliflozin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayered tablet contains: Empagliflozin 25 mg Metformin Hydrochloride IP 1000 mg (as extended release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Blue Cross Laboratories Pvt. Ltd.	11.70
18	Empagliflozin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Empagliflozin 25 mg Metformin Hydrochloride IP 1000 mg (as Extended release)	1 Tablet	M/s MSN Laboratories Pvt. Ltd.	18.75
19	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Empagliflozin 10 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Zydus Healthcare Ltd.	29.08
20	Empagliflozin, Linagliptin & Metformin	Each film coated tablet contains: Empagliflozin 10 mg, Linagliptin 5 mg,	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./	29.08

Sl. No	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
	Hydrochloride (ER) Tablets	Metformin Hydrochloride IP 1000 mg (as Extended Release)		M/s Cadila Pharmaceuticals Ltd.	
21	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Empagliflozin 10 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Glenmark Pharmaceuticals Ltd.	29.08
22	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Empagliflozin 10 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Alkem Laboratories Ltd.	28.57
23	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Empagliflozin 10 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Torrent Pharmaceuticals Ltd.	17.50
24	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Empagliflozin 25 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Zydus Healthcare Ltd.	33.13
25	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Empagliflozin 25 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Cadila Pharmaceuticals Ltd.	32.43
26	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) 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 Emcure Pharmaceuticals Ltd.	33.13
27	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Empagliflozin 25 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Glenmark Pharmaceuticals Ltd.	33.13
28	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Empagliflozin 25 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Alkem Laboratories Ltd.	30.36
29	Empagliflozin, Linagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Empagliflozin 25 mg, Linagliptin 5 mg, Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Torrent Pharmaceuticals Ltd.	19.50

Sl. No	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
30	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 1 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s USV Private Ltd.	12.82
31	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 1 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Emcure Pharmaceuticals Ltd.	12.82
32	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 1 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Alkem Laboratories Ltd.	12.82
33	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 1 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Dr. Reddys Laboratories Ltd.	12.82
34	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 1 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Zydus Healthcare Ltd.	12.82
35	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s USV Private Ltd.	14.50
36	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Emcure Pharmaceuticals Ltd.	14.50

Sl. No	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
37	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Alkem Laboratories Ltd.	14.50
38	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Eris Lifesciences Ltd.	14.50
39	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Dr. Reddys Laboratories Ltd.	14.50
40	Sitagliptin, Glimepiride & Metformin Hydrochloride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50 mg Glimepiride IP 2 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Zydus Healthcare Ltd.	14.50
41	Phenylephrine Hydrochloride & Chlorpheniramine Maleate Syrup	Each 5 ml contains: Phenylephrine Hydrochloride IP 5 mg Chlorpheniramine Maleate IP 2 mg	1 ml	M/s Vapi Care Pharma Pvt. Ltd. / M/s Apex Laboratories Pvt. Ltd.	1.01

5. Agenda item no. 5: Request for continuation of retail prices approved & notified by NPPA for M/s Torrent Pharmaceuticals Limited in respect of formulation "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".

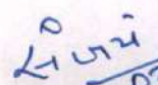
5.1 The Authority noted that M/s Torrent Pharmaceuticals Limited vide letter dated 11.12.2024 requested NPPA to permit marketing of the formulation "Each film coated tablet contains Calcium Carbonate IP 1250mg eq. to Elemental Calcium 500mg, Vitamin D3 IP 2000IU, Mecobalamin IP (Methylcobalamin) 1500mcg, L-Methylfolate Calcium 1mg, Pyridoxal - 5-Phosphate 20mg" at prices approved by NPPA notified vide S.O. no.

4062 (E) dated 08.11.2019, while shifting the manufacturing of the said formulations to its own site at Sikkim from M/s Akums Drugs and Pharmaceuticals Limited.

5.2 The Authority deliberated upon the matter in detail and noted that in the instant case since M/s Torrent Pharmaceuticals Limited has applied for the manufacturing the captioned formulation at its own site, the company may be permitted to market the said formulation at approved retail price, not exceeding the present applicable retail price.

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

This issues with the approval of Chairman, NPPA.


(Sanjay Kumar)
03/06/2025
Adviser (Cost)