

मिसिलस.- 8(130)/2025/डी.पी/एनपीपीए-डीवी-II

F. No. 8(130)/2025/DP/NPPA-Div. II

कार्यवाहीस. : 262/130/2025/F

Proceeding No: 262/130/2025/F

Minutes of the 262nd (overall) and 130th meeting of the Authority under DPCO, 2013 held on 25.02.2025 at 03:00 pm

The 262nd meeting of the Authority (overall), which is the 130th meeting under the DPCO, 2013 was held on 25th February, 2025 at 03:00 p.m. under the Chairmanship of Shri P. Krishnamurthy, Chairman, NPPA. The following Authority members were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri Manmohan Sachdeva, Additional Chief Adviser Cost (ACAC), O/o Chief Adviser (Cost), Department of Expenditure
- (iii) Shri Antony Cyriac, Economic Advisor, Department of Economic Affairs

Shri Ranga Chandrashekar, Joint Drug Controller, CDSCO, Ministry of Health & Family Welfare. (through video conferencing)

The following officers of NPPA attended the meeting and assisted the Authority in its deliberations:

- (i) Shri Sanjay Kumar, Adviser (Cost)
- (ii) Ms. Rashmi Tahiliani, Director (Pricing)
- (iii) Shri Mahaveer Saini, Deputy Director (Pricing)
- (iv) Ms. Yuvika Panwar, Assistant Director (Pricing)

1. Agenda item no. 1 - Confirmation of the Minutes of the 129th Meeting held on 29.1.2025.

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 129th Meeting held on 29.1.2025.

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 Para 5 and Para 15 of DPCO, 2013

4.1 The Authority deliberated on Fifty-four (54) cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (iv) falling under the purview of Para 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of following Fifty-three (53) 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

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in ₹)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	4(i)	Acetylcysteine & Acebrophylline Tablets	Each film coated tablet contains: Acetylcysteine BP 600 mg Acebrophylline 100 mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd. /M/s Aurobindo Pharma Ltd.	14.98
2	4(ii)	Bisoprolol Fumarate & Amlodipine Besilate Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5 mg Amlodipine Besilate eq. to Amlodipine IP 5 mg	1 Tablet	M/s Swiss Garnier Life Sciences/ M/s Workcell Solutions Pvt. Ltd.	8.54
3	4(iii)	Cefixime & Ofloxacin Oral Suspension	Each 5 ml of the reconstituted suspension contains: Cefixime Trihydrate IP eq. to Cefixime anhydrous 50 mg Ofloxacin IP 50 mg	1 ML	M/s Theon Pharmaceuticals Ltd. /M/s J.B Chemicals & Pharmaceuticals Ltd.	2.00
4	4(iv)	Cefixime Oral Suspension IP (Combipack with Sterile Water)	Each Combipack contains: (A) Cefixime Oral Suspension IP Each 5 ml of reconstituted suspension contains: Cefixime IP as Trihydrate eq. to Anhydrous Cefixime 200 mg (B) 1 Vial of Sterile Water for Injection IP Each Vial Contains:	1 ML	M/s Malik Lifesciences Pvt. Ltd./ M/s FDC Ltd.	3.72

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in ₹)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
			Sterile Water for injection IP 30 ml			
5	4(v)	Cholecalciferol (Vitamin D3) oral solution	Each 5 ml contains: Cholecalciferol IP (in nano droplet form) 60000IU	1 ML	M/s Ravenbhel Healthcare Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	Note 1
6	4(vi)	Calcium Citrate Malate & Vitamin D3 Tablets	Each film coated tablet contains: Calcium Citrate Malate IP eq. to Elemental Calcium 250 mg Vitamin D3 IP 1000 IU	1 Tablet	M/s Marine Medicare Pvt. Ltd. / M/s Alkem Laboratories Ltd.	12.31
7	4(vii)	Methylcobalamin, Alpha Lipoic Acid, Folic Acid, Pyridoxine HCl & Vitamin D3 tablets	Each film coated tablet contains: Methylcobalamin IP 1500 mcg Alpha Lipoic Acid IP 100 mg Folic Acid IP 1.5 mg Pyridoxine HCl IP 3 mg Vitamin D3 IP 1000 IU	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s Macleods Pharmaceuticals Ltd.	15.63
8	4(viii)	Paracetamol, Phenylephrine HCl & Chlorpheniramine Maleate tablets	Each uncoated tablet contains: Paracetamol IP 500 mg Phenylephrine HCl IP 10 mg Chlorpheniramine Maleate IP 2 mg	1 Tablet	M/s East African(India)Over seas/ M/s Micro Labs Ltd.	4.81
9	4(ix)	Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Suspension	Each 5 ml contains: Paracetamol IP 250 mg Phenylephrine Hydrochloride IP 5 mg Chlorpheniramine Maleate IP 2 mg	1 ML	M/s Mascot Health Series Pvt. Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	1.29
10	4(x)	Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Suspension	Each 5 ml contains: Paracetamol IP 125 mg Phenylephrine Hydrochloride IP 5 mg Chlorpheniramine Maleate IP 1 mg	1 ML	M/s Mascot Health Series Pvt. Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	1.17
11	4(xi)	Dextromethorphan Hydrobromide, Chlorpheniramine	Each film coated tablet contains: Dextromethorphan Hydrobromide IP 10 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s German	4.78

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in ₹)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
		ne Maleate & Phenylephrine Hydrochloride tablets	Chlorpheniramine Maleate IP 2 mg Phenylephrine Hydrochloride IP 5 mg		Remedies Pharmaceuticals Pvt. Ltd.	
12	4(xii)	Paracetamol & Caffeine Tablets	Each uncoated tablet contains: Paracetamol IP 650mg Caffeine IP (Anhydrous) 50 mg	1 Tablet	M/s Juggat Pharma (Pharma Division of Jagdale Industries Pvt. Ltd.)	3.61
13	4(xiii)	Ibuprofen & Paracetamol Suspension	Each 5 ml contains: Ibuprofen IP 100 mg Paracetamol IP 162.5 mg	1 ML	M/s Shiva Biogenetic Pharmaceuticals Pvt. Ltd./ M/s Lupin Life Sciences Ltd.	0.52
14	4(xiv)	Diclofenac sodium & Thiocolchicoside capsules	Each Hard Gelatin capsule contains: Diclofenac sodium IP 50 mg (as Diclofenac sodium Gastro-Resistant tablets IP) Thiocolchicoside IP 4 mg (as uncoated Thiocolchicoside tablet)	1 Capsule	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s Dr. Reddy's Laboratories Ltd.	16.90
15	4(xv)	Domperidone & Naproxen Sodium Tablets	Each film coated tablet contains: Domperidone Maleate IP eq. to Domperidone 10 mg, Naproxen Sodium USP 550 mg eq. to Naproxen 500 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	8.49
16	4(xvi)	Escitalopram Oxalate & Clonazepam tablets	Each film coated tablet contains: Escitalopram Oxalate IP Eq. to Escitalopram 20mg Clonazepam IP 0.5mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Limited / M/s Lupin Limited	19.65
17	4(xvii)	Escitalopram Oxalate & Clonazepam tablets	Each film coated tablet contains: Escitalopram Oxalate IP Eq. to Escitalopram 5 mg Clonazepam IP 0.25mg	1 Tablet	M/s Pure & Cure Healthcare Pvt. Limited / M/s Lupin Limited	7.96
18	4(xviii)	Lactulose Enema	Each ml contains: Lactulose Solution IP eq. to Lactulose 200 mg Sodium Benzoate IP 3mg (as preservative)	1 ML	M/s Naxpar Pharma Pvt. Ltd./ M/s Abbott India Ltd.	1.32



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(1)	(2)	(3)	(4)	(5)	(6)	(7)
19	4(xix)	Mefenamic Acid & Tranexamic Acid Tablets	Each Film Coated Tablet contains: Mefenamic Acid IP 250 mg Tranexamic Acid IP 500 mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Dr. Reddy's Laboratories Ltd.	33.25
20	4(xx)	Nebivolol Hydrochloride & Telmisartan tablets	Each uncoated bilayered tablet contains: Nebivolol Hydrochloride IP eq. to Nebivolol 5 mg Telmisartan IP 40 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. /M/s German Remedies Pharmaceuticals Pvt. Ltd.	15.60
21	4(xxi)	Telmisartan, Chlorthalidone & Metoprolol Succinate (ER) tablets	Each film coated bilayer tablet contains: Telmisartan IP 40 mg Chlorthalidone IP 12.5 mg Metoprolol Succinate IP 47.50 mg eq. to Metoprolol tartrate 50 mg (as Extended-release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	13.68
22	4(xxii)	Telmisartan, Cilnidipine & Metoprolol Succinate (ER) tablets	Each film coated bilayer tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Metoprolol Succinate IP 47.50 mg eq. to Metoprolol tartrate 50 mg (as Extended-release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	13.80
23	4(xxiii)	Telmisartan, Cilnidipine & Chlorthalidone tablets	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Chlorthalidone IP 12.50 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. /M/s Cadila Pharmaceuticals Ltd.	15.07
24	4(xxiv)	Telmisartan, Cilnidipine & Metoprolol Succinate (ER) tablets	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Metoprolol Succinate IP 23.75 mg eq. to Metoprolol tartrate 25 mg (as Extended-release form)	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd./ M/s Torrent Pharmaceuticals Ltd.	10.96

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in ₹)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
25	4(xxv)	Telmisartan, Cilnidipine & Metoprolol succinate (ER) tablets	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Metoprolol Succinate IP 47.50 mg eq. to Metoprolol tartrate 50 mg (as Extended-release form)	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd./ M/s Torrent Pharmaceuticals Ltd.	13.68
26	4(xxvi)	Vildagliptin (SR), Dapagliflozin & Metformin Hydrochloride (SR) tablets	Each film coated bilayered tablet contains: Vildagliptin IP 100 mg (as sustained release) Dapagliflozin propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500 mg (as sustained release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	12.50
27	4(xxvii)	Dapagliflozin, Teneligliptin & Metformin Tablets	Each film coated bilayer tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10 mg, Teneligliptin Hydrobromide Hydrate IP eq to Teneligliptin 20 mg Metformin Hydrochloride IP 500 mg (as sustained release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd. / M/s Blue Cross Laboratories Pvt. Ltd.	11.60
28	4(xxviii)	Linagliptin, Dapagliflozin & Metformin Hydrochloride (sustained release) tablets	Each film coated bilayer tablet contains: Linagliptin 5 mg Dapagliflozin propanediol USP eq. to Dapagliflozin 10mg Metformin hydrochloride IP 500mg (As Sustained release form)	1 Tablet	M/s Theon Pharmaceuticals Ltd./ M/s Akumentis Healthcare Ltd.	18.50

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in ₹)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
29	4(xxix)	Sitagliptin & Metformin Hydrochloride (Sustained Release) tablets	Each Film Coated Bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg Metformin Hydrochloride IP 1000 mg (as sustained release form)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Primus Remedies Pvt. Ltd.	13.50
30	4(xxx)	Empagliflozin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayered tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 1000 mg (as Extended-Release form)	1 Tablet	M/s Zydus Healthcare Ltd.	11.83
31	4(xxxi)	Empagliflozin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayered tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 1000 mg (as Extended Release)	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd./ M/s Alkem Laboratories Ltd.	11.83
32	4(xxxii)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Morepen Laboratories Ltd.	8.03
33	4(xxxiii)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 850 mg	1 Tablet	M/s Morepen Laboratories Ltd.	7.13
34	4(xxxiv)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Morepen Laboratories Ltd.	6.24
35	4(xxxv)	Empagliflozin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayered tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg (as Extended-Release form)	1 Tablet	M/s Zydus Healthcare Ltd.	19.01

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in ₹)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
36	4(xxxvi)	Empagliflozin & Metformin Hydrochloride (ER) Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg (as Extended-Release form)	1 Tablet	M/s-MSN Laboratories Pvt. Ltd./M/s USV Ltd.	19.01
37	4(xxxvii)	Empagliflozin & Metformin Hydrochloride (ER) Tablets	Each film coated Bilayered tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg (as Extended-Release form)	1 Tablet	M/s Pure & Cure Healthcare Pvt. Ltd./ M/s Alkem Laboratories Ltd.	19.01
38	4(xxxviii)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Cadila Pharmaceuticals Ltd.	19.01
39	4(xxxix)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Morepen Laboratories Ltd.	13.38
40	4(xl)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Emcure Pharmaceuticals Ltd.	19.01
41	4(xli)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Abbott Healthcare Pvt. Ltd.	17.85
42	4(xlii)	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 Cadila Pharmaceuticals Ltd.	18.10
43	4(xliii)	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 USV Ltd.	18.10
44	4(xliv)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Morepen Laboratories Ltd.	12.49

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in ₹)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
45	4(xlv)	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 Emcure Pharmaceuticals Ltd.	18.10
46	4(xlvi)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Intas Pharmaceuticals Ltd.	10.71
47	4(xlvii)	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 Abbott Healthcare Pvt. Ltd.	14.28
48	4(xlviii)	Empagliflozin & Metformin Hydrochloride Tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 850 mg	1 Tablet	M/s Morepen Laboratories Ltd.	12.94
49	4(xlix)	Dapagliflozin & Metoprolol Succinate (as extended release form) tablets	Each film coated bilayer tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10 mg, Metoprolol Succinate eq. to Metoprolol Tartrate (as extended release) 50 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Ltd.	17.27
50	4(l)	Dapagliflozin & Metoprolol Succinate (ER) Tablets	Each film coated bilayer tablet contains: Dapagliflozin propanediol USP eq. to Dapagliflozin 10mg Metoprolol Succinate eq. to Metoprolol Tartrate 50 mg (as extended release)	1 Tablet	M/s Exemed Pharmaceuticals / M/s Ajanta Pharma Ltd.	17.14
51	4(li)	Dapagliflozin & Metoprolol Succinate (ER) Tablets	Each film coated bilayer tablet contains: Dapagliflozin propanediol USP eq. to Dapagliflozin 10mg Metoprolol Succinate eq. to Metoprolol Tartrate 50 mg (as extended release)	1 Tablet	M/s Exemed Pharmaceuticals /M/s Cipla Ltd.	17.27

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in ₹)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
52	4(iii)	Dapagliflozin & Metoprolol Succinate (as extended-release form) tablets	Each film coated bilayer tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10 mg, Metoprolol Succinate eq. to Metoprolol Tartrate (as extended release) 25 mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Zydus Healthcare Ltd.	15.96
53	4(iiii)	Metformin oral solution	Each 5 ml oral solution contains: Metformin Hydrochloride IP 500mg	1 ML	M/s Eris Therapeutics Limited	0.40
54	4(liv)	Cefixime & Erdosteine Capsules	Each hard gelatin capsule contains: Cefixime IP eq. to Cefixime Anhydrous 200 mg Erdosteine 300 mg	1 Capsule	M/s Macleods Pharmaceuticals Ltd.	39.08

Note 1 : The Authority directed to reexamine the data as considered in the worksheet. Hence, the agenda item was deferred.

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

5.1 Noted.

6. Agenda item no. 6: Minutes of 65th meeting of Multidisciplinary Committee of Experts held on 23.1.2025

6.1 Noted.

7. Agenda item no. 7: Proposal for Filing of Form I applications on IPDMS 2.0 only w.e.f. 1.04.2025

7.1 The Authority noted that presently as per the Eco-system guidelines issued by NPPA on 26.08.2020 and OM dated 12.02.2021, applicant companies submit the Form-I application with all the requisite documents through Email.

7.2 It was further noted that IPDMS 2.0 which was launched on 29.08.2022 is functional and the companies are filing Form I applications through IPDMS 2.0 too. The

Authority also noted that during the period from 01.04.2024 to 31.01.2025, approx. 42% of Form I applications were received through IPDMS 2.0.

7.3 The Authority also noted that IPDMS 2.0 would allow the companies to know the status of their Form I applications as there is provision of sending messages when the retail prices are notified through publication in the Official Gazette and also provision can be made in IPDMS 2.0 for sending system generated mail to the companies intimating them about the uploading of the draft worksheet with respect to their Form I application. The system will also help in strengthening digital database at NPPA.

7.4 The Authority deliberated the matter and decided that w.e.f. next financial year i.e. 01.04.2025, Form I applications shall be accepted only through IPDMS 2.0 and necessary instructions in this regard may be issued.

8. Agenda item no. 8 : Ceiling price fixation of scheduled formulation under NLEM, 2022 where data available in the market data is limited.


8.1 The Authority recalled the deliberation held in its 104th, 108th and 120th meeting on 23.11.2022, 27.1.2023 and 24.1.2024 respectively regarding methodology for the ceiling price fixation.

8.2 The Authority noted that till date price fixation was based Pharmarac data only. Data from other sources like IPDMS, Web sources or as mentioned by the companies in their representation was not considered.

8.3 The Authority further noted that Pharmarac data captures limited hospital supply products and DoP also in its review order dated 27.12.2024 relating to Iohexol injection 300 mg iodine as a special case passed an order to explore other database to capture the representative market for ceiling price fixation.

8.4 The Authority deliberated upon the matter and decided that in the remaining cases of ceiling price fixation, in case the qualifying items as per Pharmarac database are less than five (5), data from other sources i.e. IPDMS Form II/ V; Web sources; market survey; or any other source may be explored for identification of other manufacturers in line with Para 9(1) of DPCO 2013.

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


(Dr. Vinod Kotwal)
Member Secretary