

Minutes of the 243rd(overall) and 111thmeeting of the Authority under DPCO, 2013 held on 29.03.2023 at 03:00 PM.

The 243rd meeting of the Authority (overall), which is the 111th meeting under the DPCO, 2013 was held on 29th March, 2023 at 11.30AM under the Chairmanship of Shri Kamlesh Kumar Pant, Chairman, NPPA. The following Authority members of NPPA were present during the meeting:

- (i) Dr. Vinod Kotwal, Member Secretary, NPPA
- (ii) Shri G. Venkatesh, Adviser (Cost), O/o Chief Adviser (Cost), Department of Expenditure

Shri A. K. Pradhan, Jt. Drug Controller, CDSCO, Ministry of Health & Family Welfare was also present.

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

- (i) Shri Manmohan Sachdeva, Advisor (Cost-I)
- (ii) Shri Sanjay Kumar, Advisor (Cost-II)
- (iii) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (iv) Shri Mahaveer Saini, Deputy Director (Pricing)
- (v) Ms. Yuvika Panwar, Asst. Director

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 110th Meeting held on 23.03.2023.

1.1 The Authority confirmed the minutes without any change.

2. Agenda item no. 2 - (a) Action Taken Report (ATR) on decisions taken by NPPA in its 110th Meeting held on 23.03.2023.

2.1 Noted.

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

3.1 Noted.

4. Agenda item no. 4 - Status of implementation of Review cases

4.1 Noted.

5. Agenda item no. 5- Change of Manufacturer by Marketing Company

5.1 The Authority noted that the retail prices of the formulations "Rosuvastatin 10mg/20mg+ Aspirin 75mg/75mg +Clopidogrel 75 mg/75 mg" with the brand names "Rosucor Gold 10" & "Rosucor Gold 20" respectively were notified vide SO. 544(E) dated 06.02.2018 for M/s Synokem Pharmaceuticals Ltd. (manufacturer)/M/s Torrent Pharmaceuticals (marketing company) based on the decision taken by the Authority in its 54th meeting dated 05.02.2018 at Rs. 9.97 and Rs.18 per capsule respectively. It was also noted that the prices of Rosuvastatin 10mg+ Aspirin 75mg +Clopidogrel 75 mg were revised to Rs. 11.70 per capsule in view of Review order dated 08.06.2018 and the decision taken by the Authority in its 59th meeting dated 08.08.2018. This was notified vide SO No. 3984 (E) dated 13.08.2018.

5.2 The Authority further noted that M/s Torrent Pharmaceuticals Ltd. have informed that due to change in business strategy, they are proposing to manufacture these formulations themselves under the existing brand. Copy of the license of CDSCO and State Licensing Authority issued to M/S Torrent Pharmaceuticals Ltd. to manufacture the said formulation has been submitted.

5.3 The Authority observed that Para 15(2) of DPCO 2013 provides for application for retail price of new drugs by the applicant company prior to its launch. However, M/s Torrent Pharmaceuticals Ltd is already marketing the subject formulation after taking retail price approval from NPPA and presently the company only intends to switch the manufacturer.

5.4 The Authority deliberated upon the matter in detail considering the permission granted to M/s Torrent Pharmaceuticals Ltd. in the 99th Authority meeting in respect of similar matter for the formulation "Chlorthalidone 12.5 mg + Telmisartan 40 mg tablet" wherein M/s Torrent Pharmaceuticals Ltd. was granted permission for change of manufacturer. The attention of the Authority was also drawn to O.M. dated 24.11.2017 issued on guidelines for examination of cases of launch of 'New Drugs' by pharma companies. Accordingly, it was decided that in case the applicant marketing company intends to change the manufacturer for a formulation having the same brand for which retail price has already been provided, it may be allowed to continue to market the formulation with the same brand with the changed manufacturer at the price not exceeding the present applicable retail price. Accordingly, the Authority decided to allow M/s Torrent Pharmaceuticals to market the formulation "Rosuvastatin 10mg/20mg+ Aspirin 75mg/75mg +Clopidogrel 75 mg/75 mg" having the same brand name "Rosucor Gold 10" & "Rosucor Gold 20" themselves at the price not exceeding the present applicable retail price i.e. price notified and increased as per the provisions of Para 20 of DPCO 2013.

5.5 The Authority also noted that the retail price of the formulation "Diclofenac Sodium IP 75 mg/ml" with the brand name "Voveran 1ml AQ" was notified vide SO No. 1894 (E)

dated 31.05.2019 for M/s Nitin Life Sciences Ltd. (manufacturer)/M/s Novartis India (marketing company) based on the decision taken in its 67th Authority meeting dated 29.05.2019 at Rs.21.92 per 1 ML pack.

5.6 The Authority further noted that M/s Novartis India Ltd has informed that in order to support environmentally sustainable business through reduction in supplier footprint, in line with Novartis commitment as per Environmental social and Governance (ESG) Policy, they plan to get the same formulation manufactured from another manufacturer i.e. M/s Sovereign Pharma Ltd., Daman under the existing brand. It was also noted that changes have been proposed in six to seven excipients by the company. The Authority deliberated upon the matter in detail. Further, CDSCO representative confirmed that the change in excipients is not substantial and no separate license is required for such a change. In view of the same, the Authority decided that M/s Novartis India may be permitted to get the formulation "Diclofenac Sodium IP 75 mg/ml" manufactured by M/s Sovereign Pharma Ltd., Daman under the existing brand "Voveran 1ml AQ" at the price not exceeding the present applicable retail price i.e. price notified and increased as per the provisions of Para 20 of DPCO 2013.

5.7 The same was allowed by the Authority in line with deliberations as above in respect of M/s Torrent Pharmaceuticals Ltd. subject to submission of (a) the copy of license of CDSCO and State Licensing Authority of M/s Sovereign Pharma Ltd., Daman to manufacture the subject formulation; and (b) the copy of joint agreement between M/s Sovereign Pharma Ltd., Daman and M/s Novartis India Ltd.

6. Agenda item no. 6- Fixation of ceiling prices of 171 scheduled formulations under NLEM 2022

6.1 The Authority noted that the methodology for fixation of ceiling price of scheduled formulations under revised Schedule-I (NLEM, 2022) was deliberated in the 104th meeting of the Authority held on 23.11.2022. Based on the approved methodology, ceiling prices for formulations are uploaded on the NPPA website for 10 working days to invite comments in compliance to O.M. No. F. NO. 31015/44/2016-PI.I dated 11.07.2016 issued by Department of Pharmaceuticals. The details of draft working sheets uploaded are given in the table below.

Status of draft working sheets uploaded on the NPPA website

S.No.	Date of upload of draft working sheets	10 days completed on	No. of formulations uploaded	Approved in earlier meetings	No. of formulations proposed for approval
1.	25.11.2022	09.12.2022	121	119	-
2.	01.12.2022	15.12.2022	43-3 (Re-uploaded)	40	-
3.	02.12.2022	16.12.2022	51-1	50	-

S.No.	Date of upload of draft working sheets	10 days completed on	No. of formulations uploaded	Approved in earlier meetings	No. of formulations proposed for approval
			(Re-uploaded)		
4.	05.12.2022	19.12.2022	15	15	-
5.	13.12.2022	27.12.2022	69-1 (Re-uploaded)	68	-
6.	20.12.2022	03.01.2023	30	30	-
7.	23.12.2022	06.01.2023	35-1 (Re-uploaded)	34	-
8.	06.01.2023	20.01.2023	45	44	-
9.	28.01.2023	10.02.2023	42 - 1 + 3 (Re-uploaded)	44	-
10.	02.02.2023	16.02.2023	54 - 5 + 1 (Re-uploaded)	33	16
11.	09.02.2023	23.02.2023	49 - 4 + 1 (Re-uploaded)	-	46
12.	10.02.2023	24.02.2023	50	-	47
13.	14.02.2023	28.02.2023	3 (Revised)	-	3
14.	15.02.2023	01.03.2023	24+ 2 (Re-uploaded)	-	26
15.	03.03.2023	20.03.2023	24 + 9 (Re-uploaded)	-	31
16.	Separate ceiling price for special feature approved		-	2	-
17.	Hormone releasing IUD and IUD containing copper		2	2	-
18.	Insulin Soluble and Premix Insulin 30:70 Injection (Regular: NPH)		2	-	2
	Total		659	481	171

6.2 The Authority was apprised that a total of 1065 representations have been received from companies within the prescribed time period of 10 working days till 21.03.2023. Companies have submitted copy of invoice(s) showing the revised PTR and/ or snapshots of sample pack showing revised MRP. The representations are broadly related to:

(a) Related to data in worksheets:

- i. Price to Retailer considered as per July, 2022 Pharmatrac database is not reflecting the WPI increase availed by the companies in April, 2022
- ii. Incorrect pack sizes
- iii. Considering MR variant along with conventional variant in cases where MR variant is separately included in schedule.

- iv. Notification of price from per pack to per ml basis/ fixation of price for various pack sizes

These claims have been cross verified with the Form-II/Form-V submitted by the companies till 15.05.2022 in IPDMS as per provisions of DPCO, 2013. Form-V for the formulations newly added in the schedule-I (NLEM, 2022) are cross verified till 31.07.2022, since the July 2022 database is considered under Para 9(7) of DPCO,2013.

(b) Related to methodology:

- i. Representations received on methodology are same as already deliberated in 105th meeting of Authority held on 15.12.2022.
- ii. Representations on methodology of newly added formulations under NLEM, 2022 where Inter-brand variation is observed more than 10% under Para 19 of DPCO, 2013

Agenda item no. 6(i)

1. Fixation of ceiling prices of 82 scheduled formulations under Para 4 of DPCO 2013.

The Authority deliberated upon the price fixation of 82 scheduled formulations as below and approved the following under Para 4 of DPCO 2013:

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./ Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1	6.1.2.3	Ivermectin	Tablet 6mg	New Added	New Added	19.25	1 Tablet
2	6.1.2.3	Ivermectin	Tablet 12mg	New Added	New Added	33.33	1 Tablet
3	10.1.1	Diltiazem	Tablet 30mg	2.66	SO1499 dated 30.3.22	2.39	Per Tablet
4	11.1.1	Clotrimazole	Lotion 1%	3.98	SO1499 dated 30.3.22	3.47	1 ML
5	6.2.1.1	Amoxicillin	Oral liquid 250 mg/5 mL (p)	1.5	SO1499 dated 30.3.22	1.39	1 ML

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
6	26.4	Cholecalciferol	Capsule 60000 IU	32.79	SO1499 dated 30.3.22	27.45	1 Capsule
7	7.1.32	Paclitaxel (Note 2)	Injection 30 mg/5 mL, injection 100 mg/16.7 ml and all injections of similar ratio of strength	228.33	SO1499 dated 30.3.22	192.14	1 ML
8	1.2.1	Bupivacaine	Injection 0.5 % with 7.5 % glucose	6.89	SO1499 dated 30.3.22	6.59	1 ML
9	6.7.6.1	Azithromycin	Tablet 1000mg	New Added	New Added	51.53	1 Tablet
10	3.5	Pheniramine	Injection 22.75mg/mL (2ml)	2.54	SO1499 dated 30.3.22	2.46	1 ML
11	10.2.4	Esmolol	Injection 10 mg/mL	24.06	SO1499 dated 30.3.22	23.53	1 ML
12	8.2.1	Enoxaparin (Note 1)	Injection 40mg/0.4mL, injection 60mg/0.6 ml and all injections of similar ratio of strength i.e.100mg/1 ml	112.86	SO1499 dated 30.3.22	99.87	0.10 ML
13	11.5.1	Permethrin	Cream 5%	1.93	SO1499 dated 30.3.22	1.65	1 GM
14	12.2.3	Iohexol	Injection 300mg iodine/mL	18.46	SO1499 dated 30.3.22	15.07	1 ML

ML

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./ Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
15	20.2	Caffeine	Injection 20mg/mL	278.7	SO1499 dated 30.3.22	223.41	Per ML
16	11.5.1	Permethrin	Lotion 1%	1.01	SO1499 dated 30.3.22	0.89	1 ML
17	26.4	Cholecalciferol	Capsule 1000 IU	5.31	SO1499 dated 30.3.22	4.36	1 Capsule
18	26.4	Cholecalciferol	Sachet/Granules/Powder 60000 IU	New Added	New Added	30.31	1 GM
19	1.2.1	Bupivacaine	Injection 0.5 %	4.35	SO1499 dated 30.3.22	3.94	1 ML
20	19.3.9	Tetanus Toxoid	As licensed (5ml)	26.03	SO1499 dated 30.3.22	22.77	1 Vial
21	26.8	Vitamin A	Tablet 50000IU (including Chewable Tablet)	0.78	SO1499 dated 30.3.22	0.65	1 Tablet
22	26.8	Vitamin A	Injection 50000 IU/mL	2.13	SO1499 dated 30.3.22	2.02	1 ML
23	19.3.9	Tetanus Toxoid	As licensed (0.5ml)	12.04	SO1499 dated 30.3.22	11.12	1 Vial (0.5ML)
24	24.1.1	Budesonide (Note 3)	Respirator solution for use in nebulizer 0.5mg/mL	11.90	SO1499 dated 30.3.22	10.61	1 ML

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./ Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
25	26.1	Ascorbic acid (Vitamin C)	Tablet 100mg	0.21	S01499 dated 30.3.22	0.21	1 Tablet
26	26.1	Ascorbic acid (Vitamin C)	Tablet 500mg	1.53	S01499 dated 30.3.22	1.32	1 Tablet
27	3.3	Dexamethasone	Tablet 4 mg	New Added	New Added	4.12	1 Tablet
28	6.5.2	Clotrimazole	Pessary 100mg	9.65	S01499 dated 30.3.22	8.93	1 Pessary
29	16.3	Clotrimazole	Drops 1%	3.37	S01499 dated 30.3.22	3.01	1 ML
30	24.1.1	Budesonide (Note 3)	Respirator solution for use in nebulizer 1mg/mL	14.34	S01499 dated 30.3.22	11.72	1 ML
31	10.5.1	Acetylsalicylic acid	Enteric coated Tablet 75 mg	1.36	S01499 dated 30.3.22	0.31	1 Tablet
32	10.5.1	Acetylsalicylic acid	Conventional /Effervescent /Dispersible/ Enteric coated Tablets 150 mg	1.34	S01499 dated 30.3.22	0.63	1 Tablet
33	18.1.4	Methylprednisolone	Injection 40mg/mL	59.92	S01499 dated 30.3.22	40.73	1 ML
34	11.1.1	Clotrimazole	Cream 1%	3.23	S01499 dated 30.3.22	2.68	1 GM
35	11.5.1	Permethrin	Cream 1%	1.78	S01499 dated 30.3.22	1.34	1 GM
36	7.4.7	Haloperidol	Injection 5mg/mL	6.47	S01499 dated 30.3.22	5.81	1 ML



S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
37	6.1.1.1	Albendazole	Oral liquid 200mg/5mL (p)	1.77	SO1499 dated 30.3.22	1.6	1 ML
38	11.5.1	Permethrin	Lotion 5%	1.09	SO1499 dated 30.3.22	0.89	1 ML/GM
39	7.1.19	Doxorubicin	Injection 2mg/mL	39.86	SO1499 dated 30.3.22	28.32	1 ML
40	6.2.1.8	Cefixime	Capsule 200mg	16.03	SO1499 dated 30.3.22	13.09	1 Capsule
41	6.2.2.1	Azithromycin	Capsule 250mg	11.66	SO1499 dated 30.3.22	9.47	1 Capsule
42	21.4.1	Acetazolamide	Capsule 250mg	5.02	SO1499 dated 30.3.22	4.50	1 Capsule
43	3.5	Pheniramine	Injection 22.75mg/mL (10ml)	1.89	SO1499 dated 30.3.22	1.84	1 ML
44	2.4.3	Methotrexate	Tablet 5mg	9.29	SO1499 dated 30.3.22	8.41	1 Tablet
45	7.1.24	Ifosfamide	Powder for Injection 2000mg	1054.59	SO1499 dated 30.3.22	573.59	1 Vial
46	6.10.2.1	Doxycycline	Tablet 100mg	1.09	SO1499 dated 30.3.22	1.09	1 Tablet
47	7.4.9	Loperamide	Capsule 2mg	3.98	SO1499 dated 30.3.22	3.38	1 Capsule
48	10.1.4	Metoprolol	Capsule 25mg	4.7	SO1499 dated 30.3.22	3.69	1 Capsule
49	10.1.4	Metoprolol	Capsule 50mg	7.16	SO1499 dated 30.3.22	5.19	1 Capsule
50	7.1.25	Imatinib	Capsule 100mg	86.2	SO1499 dated 30.3.22	65.54	1 Capsule
51	6.5.3	Fluconazole	Capsule 200mg	40.54	SO1499 dated 30.3.22	35.77	1 Capsule

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./ Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
52	6.5.3	Fluconazole	Capsule 150mg	20.59	SO1499 dated 30.3.22	17.14	1 Capsule
53	22.2.2	Nifedipine	Capsule 10mg	0.95	SO1499 dated 30.3.22	0.85	1 Capsule
54	17.4.1	Dicyclomine	Injection 10mg/mL (Less than 10ML)	3.54	SO1499 dated 30.3.22	2.96	1 ML
55	19.3.4	Hepatitis B vaccine	As Licensed	86.95	SO1499 dated 30.3.22	70.3	1 ML
56	1.2.3	Lignocaine (A) +Adrenaline(B)	Injection 2%(A)+ 1:200000(5 mcg/mL)(B)	1.02	SO1499 dated 30.3.22	0.94	1 ML
57	17.6.1	Oral rehydration salts	As licensed	0.16	SO1499 dated 30.3.22	0.13	1 ML
58	5:2.1.3	Propranolol	Capsule 40mg	4.22	SO1499 dated 30.3.22	3.79	1 Capsule
59	19.3.2	DPT+ Hib+ HepB vaccine	As licensed	89.18	SO1499 dated 30.3.22	67.47	Per 0.1 ML
60	6.1.1.1	Albendazole	Tablet 400mg	8.55	SO1499 dated 30.3.22	6.28	1 Tablet
61	17.1.1	Omeprazole	Tablet 20 mg	5.47	SO1499 dated 30.3.22	3.87	1 Tablet
62	6.2.2.10	Nitrofurantoin	Capsule 100 mg	8.72	SO1499 dated 30.3.22	7.71	1 Capsule
63	10.3.5	Ramipril	Capsule 2.5mg	5.26	SO1499 dated 30.3.22	4.16	1 Capsule
64	6.1.1.1	Albendazole	Chewable Tablet 400mg	8.55	SO1499 dated 30.3.22	7.25	1 Tablet
65	22.2.1	Betamethasone	Injection 4mg/mL	4.66	SO1499 dated 30.3.22	4.23	1 ML
66	10.3.5	Ramipril	Capsule 5mg	8.21	SO1499 dated 30.3.22	6.41	1 Capsule
67	1.1.7	Sevoflurane	Liquid for inhalation	33.21	SO1499 dated	27.8	1 ML

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./ Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
					30.3.22		
68	11.3.2	Calamine	Lotion (As per IP)	0.94	SO1499 dated 30.3.22	0.85	1 ML
69	23.4.1	Clomipramine	Tablet 10 mg	2.79	SO1499 dated 30.3.22	2.54	1 Tablet
70	23.4.1	Clomipramine	Tablet 25 mg	6.16	SO1499 dated 30.3.22	5.55	1 Tablet
71	23.4.1	Clomipramine	Tablet 75 mg	15.93	SO1499 dated 30.3.22	14.68	1 Tablet
72	17.7.1	Somatostatin	Powder for Injection 3mg	1759.69	SO1499 dated 30.3.22	1212.01	1 Vial
73	19.2.5	Hepatitis B immunoglobulin	As Licensed	6116.13	SO1499 dated 30.3.22	4903.95	1 Vial
74	6.2.2.6	Co-trimoxazole [Sulphamethoxazole (A) + Trimethoprim (B)]	Oral liquid 200 mg (A) + 40 mg(B)/5mL (p)	0.37	SO1499 dated 30.3.22	0.31	1 ML
75	3.3	Dexamethasone (Note 4)	Injection 4mg/mL (pack of 2ML)	10.35	SO1499 dated 30.3.22	Deferred	
76	3.3	Dexamethasone (Note 4)	Injection 4mg/mL (pack of 10ML)	15.29	SO1499 dated 30.3.22	1.4	1 ML
77	3.3	Dexamethasone (Note 4)	Injection 4mg/mL (pack of 20 ML)	29.31	SO1499 dated 30.3.22	1.2	1 ML
78	3.3	Dexamethasone (Note 4)	Injection 4mg/mL (pack of 30ML)	39.17	SO1499 dated 30.3.22	0.8	1 ML
79	6.2.2.8	Gentamicin (Note 4)	Injection 40mg/mL (pack of 2ML)	9.35	SO1499 dated 30.3.22	Deferred	
80	6.2.2.8	Gentamicin (Note 4)	Injection 40mg/mL (pack of 10ML)	19.95	SO1499 dated 30.3.22	1.35	1 ML
81	6.2.2.8	Gentamicin (Note 4)	Injection 40mg/mL	30.24	SO1499 dated	1.38	1 ML

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./ Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
			(pack of 20ML)		30.3.22		
82	6.2.2.8	Gentamicin (Note 4)	Injection 40mg/mL (pack of 30ML)	33.1	SO1499 dated 30.3.22	1.1	1 ML

The Authority noted the following with respect to above formulations:

Note 1: Enoxaparin Injection of strength 40mg/0.4ml and 60 mg/0.6 ml are mentioned in section 8.2.1 of Schedule-I of DPCO, 2013. The ceiling price fixed under NLEM, 2015 is Rs. 112.86 per 0.1 ml for both 40mg/0.4ml and 60mg/0.6ml but notified separately. The other strengths of the Enoxaparin injection (300mg/3ml, 80mg/0.8ml, 20 mg/0.2ml) are also in market with same ratio i.e. 10mg/0.1ml. Therefore, the draft working sheet was uploaded considering all the strengths with same ratio. However, representations were received stating that only ceiling prices for two packs i.e. Injection 40mg/0.4ml and 60 mg/0.6 ml may be considered as included under Schedule-I. In this context, opinion of SNCM was earlier obtained for 300mg/3ml and reply received vide letter dated 30.05.2022 states that:

Enoxaparin sodium Injection IP 300mg/ 3mL is essentially of same strength as Injection 40 mg / 0.4 mL or Injection 60 mg/ 0.6 mL.

In Report of the Core-Committee for Revision of National List of Essential Medicines, 2015, it is already mentioned which is self explanatory.

Page no-7 last paragraph "Any dosage form of a medicine, other than the dosage form included in NLEM, but in same strength and route of administration, which does not have significant difference in terms of pharmacokinetics/pharmacodynamics/ efficacy-safety profile over the dosage form mentioned in the list will be considered as included".

Thus, Enoxaparin Sodium Injection IP 3 mL multi-dose vial 300mg/mL in which each ml contains Enoxaparin Sodium IP 100 mg (10,000 anti-Xa IU)" may be considered as scheduled formulation under NLEM 2015.

In view of the above, the Authority deliberated that one ceiling price for Enoxaparin injection 40mg/0.4ml and 60 mg/0.6 ml may be notified and the following note may be given in the notification for clarification:



"The ceiling prices fixed for Enoxaparin Injection 40mg/0.4ml and 60 mg/0.6 ml at S.No.12 are also applicable to any other strengths (such as 300mg/3ml, 80mg/0.8ml, 20mg/0.2ml etc.) of the Enoxaparin with same ratio i.e. 10mg/0.1ml)."

Note 2: Paclitaxel Injection of strength 30 mg/5 mL and 100mg/16.7 ml are mentioned in section 7.1.32 of Schedule-I of DPCO, 2013. The ceiling price fixed under NLEM, 2015 is Rs. 228.33 per ml for both 30 mg/5 mL and 100mg/16.7 ml but notified separately. The other strengths of the Paclitaxel injection (300mg/50ml, 260mg/43.4ml, 250mg/41.7ml, 200 mg/33.4ml) are also in market with same ratio i.e. 6mg/ml. Therefore, the draft working sheet was uploaded considering all the strengths with same ratio. However, representations were received stating that only ceiling prices for two packs i.e. Injection 30 mg/5 mL and 100mg/16.7 ml may be considered as included under Schedule-I.

The Authority noted that issue is similar to Enoxaparin Injection as detailed in Note 1 above. Therefore, it decided that one ceiling price for Paclitaxel Injection 30 mg/5 mL and 100mg/16.7 ml may be notified and the following note may be given in the notification for clarification:

"The ceiling prices fixed for Paclitaxel Injection 30 mg/5 mL and 100mg/16.7 ml at S.No.7 are also applicable to any other strengths (300mg/50ml, 260mg/43.4ml, 250mg/41.7ml, 200mg/33.4ml etc.) of the Paclitaxel with same ratio i.e. 6mg/ml)."

Note 3: Budesonide Respirator Solution For the formulation mentioned under in S. No. 24 and 30 i.e., Budesonide Respirator solution for use in nebulizer 0.5mg/mL and Budesonide Respirator solution for use in nebulizer 1mg/mL are mentioned in section 24.1.1 of Schedule-I of DPCO, 2013. However, from the market database, it was observed that Budesonide Respirator Solution for use in nebulizer 0.5mg and 1 mg are available in Respules of 2ml.

Therefore, 2ml Respules of 0.5mg and 2ml Respules of 1mg are considered in draft working sheet for calculating ceiling prices of pack sizes of 0.5 mg in 2 ml and 1 mg in 2 ml respectively. This approach is same as followed in ceiling price fixation under NLEM, 2015. Some companies have represented against the draft worksheet stating that 2ml Respules of 1mg should be considered for 0.5mg/ml and 2ml Respules of 0.5mg should be treated as non-scheduled. However, M/s Cipla Limited having market share of 80% has not raised this issue. Therefore, it was deliberated that the following note may be given in the notification:

"The ceiling prices fixed for Budesonide Respirator solution for use in nebulizer 0.5mg/mL and Budesonide Respirator solution for use in nebulizer 1mg/mL are also applicable to 2ml Respules of 0.5mg and 2ml Respules of 1mg by applying 2 times of the ceiling prices of 1 ml Respules of 0.5 mg and 1 mg respectively."

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Note 4: Gentamicin 40mg/ml and Dexamethasone 4mg/ml: The Authority deliberated upon the matter and decided that ceiling prices may be fixed on per-ml basis for different pack sizes existing in the market instead of making the range for pack sizes as proposed.

The Authority further directed to revise the worksheet for Gentamycin (2 ML pack) excluding the pack of 1.5 ML and also fix separate ceiling price for 1.5 ML pack.

The Authority further directed to revise the worksheet for Dexamethasone (2 ML pack) excluding the pack of 5 ML and also fix separate ceiling price for 5 ML pack.

2. Fixation of ceiling prices of 54 scheduled formulations under Para 6 of DPCO 2013

The Authority deliberated upon the prices of 54 scheduled formulations as given below and approved the same under Para 6 of DPCO 2013:

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./ Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1	6.4.7	Ethambutol	Tablet 200mg	1.17	S01499 dated 30.3.22	1.02	1 Tablet
2	2.2.3	Tramadol	Capsule 50mg	5.01	S01499 dated 30.3.22	4.30	1 Capsule
3	17.1.1	Omeprazole	Capsule 10 mg	2.35	S01499 dated 30.3.22	2.15	1 Capsule
4	7.1.14	Cyclophosphamide	Tablet 50mg	4.50	S01499 dated 30.3.22	3.33	1 Tablet
5	2.2.3	Tramadol	Capsule 100mg	10.66	S01499 dated 30.3.22	8.06	1 Capsule
6	23.1.3	Haloperidol	Tablet 20mg	5.47	S01499 dated 30.3.22	4.78	1 Tablet
7	6.2.2.10	Nitrofurantoin	Oral liquid 25mg/5ml. (p)	0.91	S01499 dated 30.3.22	0.79	1 ML
8	2.4.1	Azathioprine	Tablet 25mg(p)	New Added	New Added	6.46	1 Tablet

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./ Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
9	5.1.5	Lorazepam	Injection 2mg/mL	8.63	SO1499 dated 30.3.22	7.22	1 ML
10	17.1.1	Omeprazole	Powder for oral liquid 20mg	1.36	SO1499 dated 30.3.22	1.35	1 GM
11	6.2.1.1	Amoxicillin	Powder for Injection 250 mg	New Added	New Added	22.11	1 Vial
12	15.3	Mannitol	Injection 10%	0.18	SO1499 dated 30.3.22	0.17	1 ML
13	6.2.1.1	Amoxicillin	Powder for Injection 500 mg	New Added	New Added	48.74	1 Vial
14	10.1.1	Diltiazem	Injection 5mg/mL	3.51	SO1499 dated 30.3.22	3.12	Per ML
15	10.1.4	Metoprolol	Injection 1mg/mL	New Added	New Added	3.03	1 ML
16	22.1.5	Oxytocin	Injection 10IU/mL	43.74	SO1499 dated 30.3.22	35.56	1 ML
17	25.1.6	Sodium bicarbonate	Injection (as per IP) - 7.5%	1.56	SO1499 dated 30.3.22	0.9	1 ML
18	6.5.3	Fluconazole	Injection 200mg/100 mL	118.17	SO1499 dated 30.3.22	82.34	Per 100 ML Vial
19	15.1	Furosemide	Oralliquid 10mg/mL	3.07	SO1499 dated 30.3.22	2.96	1 ML
20	2.1.4	Mefenamic acid	Tablet 250 mg	2.15	SO1499 dated 30.3.22	1.88	1 Tablet
21	26.5	Pyridoxine	Tablet 10mg	0.12	SO1499 dated 30.3.22	0.1	1 Tablet
22	6.10.1.7	Quinine	Injection 300 mg/mL	11.29	SO1499 dated 30.3.22	8.47	1 ML
23	6.10.1.6	Primaquine	Tablet 2.5mg	1.73	SO1499 dated 30.3.22	1.56	1 Tablet
24	1.2.2	Lignocaine (Note 1)	Injection 1%	8.82	SO1499 dated 30.3.22	7.91	1 ML
25	1.2.2	Lignocaine	Injection 5% with 7.5%	4.09	SO1499 dated	3.12	1 ML

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./ Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
			glucose		30.3.22		
26	7.4.10	Metoclopramide	Injection 5mg/mL (10 ML & More Pack)	1.58	SO1499 dated 30.3.22	1.45	1 ML
27	6.2.2.3	Ciprofloxacin	Oral liquid 250mg/5mL (p)	0.7	SO1499 dated 30.3.22	0.66	1 ML
28	11.4.1	Benzoylperoxide	Gel 2.5 %-5 % (3.5%)	Not fixed	Not fixed	9.02	1 GM
29	8.2.3	Phytomenadione (Vitamin K1)	Tablet 10mg	16.13	SO1499 dated 30.3.22	12.97	1 Tablet
30	6.7.2.1	Efavirenz	Tablet 200 mg (p)	25.18	SO1499 dated 30.3.22	20.1	1 Tablet
31	1.2.1	Bupivacaine	Injection 0.2 5%	2.72	SO1499 dated 30.3.22	2.52	1 ML
32	10.1.2	Glyceryl trinitrate	Sublingual Tablet 0.5mg	2	SO1499 dated 30.3.22	1.13	1 Tablet
33	5.1.9	Phenytoin	Modified Release Tablet 300mg	6.45	SO1499 dated 30.3.22	5.86	1 Tablet
34	5.1.9	Phenytoin	Tablet 100mg	1.73	SO1499 dated 30.3.22	1.57	1 Tablet
35	7.4.4	Diazepam	Tablet 2 mg	1.67	SO1499 dated 30.3.22	1.28	1 Tablet
36	5.1.9	Phenytoin	Tablet 50mg	0.82	SO1499 dated 30.3.22	0.75	1 Tablet
37	6.6.1.1	Acyclovir	Oral liquid 400mg/5mL (p)	1.41	SO1499 dated 30.3.22	1.21	1 ML
38	5.1.9	Phenytoin	Oral liquid 30mg/5 mL (p)	0.34	SO1499 dated 30.3.22	0.31	1 ML
39	5.1.9	Phenytoin	Oral liquid 125mg/5mL (p)	1	SO1499 dated 30.3.22	0.98	1 ML
40	5.1.3	Diazepam	Suppository 5mg	6.63	SO1499 dated 30.3.22	5.52	1 Suppository
41	6.2.2.13	Vancomycin	Capsule 250mg	New Added	New Added	135.91	1 Capsule

S.No.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling Prices		New Ceiling Price	Unit
				(Rs./ Unit)	SO & dated		
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
42	5.2.1.3	Propranolol	Capsule 20mg	New Added	New Added	2.10	1 Capsule
43	17.4.1	Dicyclomine	Injection 10mg/mL (10 ML & more pack))	2.28	SO1499 dated 30.3.22	1.87	1 ML.
44	5.2.1.3	Propranolol	Capsule 10mg	Not fixed	Not fixed	1.78	1 Capsule
45	17.1.1	Omeprazole	Tablet 40 mg	9.25	SO1499 dated 30.3.22	7.54	1 Tablet
46	7.1.24	Ifosfamide	Powder for Injection 1000mg	401.77	SO1499 dated 30.3.22	284.46	1 Vial
47	5.1.9	Phenytoin	Capsule 300mg	4.23	SO1499 dated 30.3.22	4.15	1 Capsule
48	5.1.9	Phenytoin	Capsule 100mg	1.69	SO1499 dated 30.3.22	1.63	1 Capsule
49	6.4.5	Cycloserine	Tablet 250mg	51.83	SO1499 dated 30.3.22	41.04	1 Tablet
50	10.2.3	Digoxin	Oral liquid 0.05mg/mL	1.41	SO1499 dated 30.3.22	1.31	1 ML.
51	10.2.3	Digoxin	Injection 0.25mg/mL.	3.7	SO1499 dated 30.3.22	3.45	1 ML.
52	6.5.1	Amphotericin B	Amphotericin B (conventional) - Injection 50mg/vial	343.91	SO1499 dated 30.3.22	202.81	1 Vial
53	6.4.11	Linezolid	Tablet 300mg	New Added	New Added	20.20	1 Tablet
54	6.2.2.6	Co-trimoxazole [Sulphamethoxazole (A) + Trimethoprim (B)]	Tablet 400 mg (A) + 80 mg (B)	0.86	SO1499 dated 30.3.22	0.80	1 Tablet

Note 1: Authority noted that the ceiling price for Lignocaine Injection 1% was uploaded on NPPA website on per pack basis. However, the only line item considered in the worksheet has pack size of 1ml. The Authority deliberated on the matter and decided to fix the ceiling price for Lignocaine Injection 1% on Per ML basis.

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3. The Authority noted that ceiling prices of Insulin (Soluble), Intermediate Acting (NPH) Insulin and Premix Insulin 30:70 Injection (Regular: NPH) were uploaded in a single worksheet at Rs.15.15 per ml. However, while placing the matter for approval of Authority only Insulin Intermediate Acting (NPH) was mentioned and inadvertently, insulin (soluble) and Premix Insulin 30:70 Injection (Regular: NPH) were not mentioned. Hence, ceiling price of Insulin Intermediate Acting (NPH) only could be notified vide SO No. 879 dated 24.02.23. The Authority approved the ceiling price of Insulin (Soluble) and Premix Insulin 30:70 Injection (Regular: NPH) at Rs. 15.15 per ml.
4. The Authority noted that ceiling prices of following three formulations as already notified under NLEM 2022 vide SO numbers mentioned in the table below required revision. It was noted that the revised prices were uploaded for 10 working days on 14.02.2023.
- I. The Authority noted that in case of Levothyroxine Tablet 150 mcg and Metoclopramide Oral liquid 5mg/5mL(p) the ceiling price had to be calculated applying monopoly restriction under Para 6, since PTR of all qualified line items was same. However, inadvertently such restriction was not applied and prices were notified without applying monopoly restriction. After deliberations the revised prices as mentioned in column no. 6 were approved.
- II. The Authority noted that in case of Ondansetron Tablet 8mg the representation was received from M/s Alkem Laboratories Limited for brand name ONDEM and ONDEM MD. However, inadvertently only ONDEM was corrected based on representation. Further, M/s Alkem Laboratories Limited has filed representation dated 06.01.2023 and hence, revision was required in for correction in PTR of ONDEM MD also. After deliberations the prices as mentioned in column No. 6 were approved.

The Authority deliberated upon the matter and approved the revised uploaded ceiling prices as mentioned in column No. 6 below:

S.No (1)	Section (2)	Formulations (3)	Dosage form(s) and strength (s) (4)	Notified Ceiling Price under NLEM 2022 & So No. & date (5)	New Ceiling Price(6)	Unit
1	18.6.2	Levothyroxine	Tablet 150mcg	Rs.1.59 per tablet vide SO No.5938 (E) dated 19.12.2022	1.52	1 Tablet
3	7.4.10	Metoclopramide	Oral liquid 5mg/5mL (p)	Rs. 0.45 per ML vide SO No.194(E) dated 11.01.2023	0.45	1 ML
2	7.4.14	Ondansetron	Tablet 8 mg	Rs.7.94 per tablet vide SO No.87 (E) dated 06.01.2023	8.08	1 Tablet

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Agenda item no. 6(ii)- Fixation of ceiling price of newly added formulations in NLEM, 2022, where Inter-brand variation is observed more than 10% under Para 19 of DPCO, 2013

The Authority noted that various representations have been received from pharma companies as well as industry associations against the methodology of restricting PTR plus 10% while fixing ceiling price of select newly included formulations in NLEM 2022 involving inter-brand PTR variation of more than 10% of the same company under Para 19 of DPCO 2013. The Authority examined the various representations, issues raised therein and deliberated as under:

- (a) The newly added formulations are considered to be essential medicines and have been included in the NLEM, 2022 for the first time based on the recommendations of the Standing National Committee on Medicines (SNCM). The 2022 Report of the SNCM notes that *"Out-of-pocket expenditure constitutes over 60% of total health expenditure, with a substantial 40% being incurred on medicines. With this background, it is of paramount importance that accessibility and affordability of medicines be enhanced in order to reduce the financial burden on the households."*

The Authority also noted that CCI in its 18th November 2021 report "Market Study on the Pharmaceutical Sector in India" has provided empirical evidence on large price variation amongst brands of the same formulation. It has been noted in the report that *"As evidenced by the data, despite the seemingly strong generic competition, gauged in terms of the number of players present in each therapeutic area and at the level of formulations/molecules, consumers in India ostensibly pay a premium for brands"*.

The same formulation of one company having multiple prices for different brands and brands having inbuilt margins and high profits coupled with information asymmetry in the pharmaceutical sector, make many drugs beyond the reach of common man and also leads to financial burden / impoverishment. This is an extra-ordinary situation working against public welfare. Therefore, it is essential to undertake an exercise to reduce the inter-brand price difference of the same company in the public interest in respect of schedule formulations since these are considered to be essential medicines that should be available at affordable prices and should not fall out of price control.

Hence, after observing high inter-brand variations of same formulation of a company, an exercise to reduce the inter-brand price difference while fixing the ceiling prices of the formulations has been done by capping at price of the lowest brand/ pack size plus 10%, an existing reference under DPCO 2013.

Also, NPPA has been invoking powers under Para 19 in certain cases in the public interest to make drugs affordable with indefinite period. For example, Vitamin A, Vitamin C, Anti-tetanus immunoglobulin & Glycerin etc.

- (b) **There has been no midway change in the methodology which is leading to inconsistency as represented by few companies and industry associations.** In all the cases of inter-brand variation of more than 10% in PTR of the formulations that have been included under NLEM 2022 for the first time, the PTR of various brands/ pack sizes of a formulation of a particular company have been capped at price of the lowest brand/ pack size plus 10%, an existing reference under DPCO 2013. Further, in order to ensure transparency, all the draft working sheets are uploaded on website for inviting any representation and the final working sheets based on which final ceiling prices are notified are also uploaded on website after notification.
- (c) **NPPA has not considered the PTR of the brands having market share of less than 1% while computing 'Average Price to Retailer' for working out the ceiling prices as stated in the representations.** For dealing with the cases of price violations, DPCO, 2013 does not differentiate between the formulations on the basis of the market share. Further as requested by the companies, the PTR of brands with 0% market share has not been considered while determining the lowest PTR for applying price restriction on other brands of the same company.
- (d) As per Para 20 (1) of DPCO, 2013, where the increase in the prices of non-scheduled formulations is beyond 10% of MRP, the manufacturer shall reduce the same to the level of 10% of MRP for next twelve months. Hence, in the cases where non-scheduled formulations have come within the purview of NLEM, 2022 for the first time, if the inter-brand variation in the price of same formulation of a company is more than 10%, the manufacturer is bound to reduce the price to the level of 10%. In view of this, for the formulations that have been included under NLEM 2022 for the first time, the PTR of various brands/ pack sizes of a formulation of a particular company have been capped at price of the lowest brand/ pack size plus 10%, an existing reference under DPCO 2013 and the ceiling prices have been calculated as per the methodology prescribed as per Para 4 or Para 6 of DPCO, 2013, as the case may be. Further, monitoring under Para 20 is done at the formulation level and not at brand level. Any violation of Para 20 should not form basis for fixation of ceiling prices under NLEM, 2022. Hence, the present methodology is as per the provisions of DPCO, 2013. Therefore, the contention made in the representations that two different methodologies have been applied for Common Formulations and Newly included formulations under NLEM 2022 is not tenable.
- (e) The price fixation under NLEM2022 of such formulations where inter-brand variation of the same company is higher than 10% has been done in public interest. Also, the present methodology of capping inter brand variation is entirely different from the exercise undertaken in 2014 which was based on

intercompany variation in MRP and hence is not comparable with present methodology which is as per provisions of DPCO, 2013.

- (f) The decision in this regard has been taken after due deliberations and non-compliance of the provision of DPCO cannot be ignored. Further, the non-compliance with the various review orders quoted in the representations is also not tenable as these review orders are related to different subject matters.

In view of above deliberations, the Authority decided to notify the prices of following 26 newly added formulations in NLEM 2022 under Para 19 of DPCO 2013 and 1 newly added formulation under Para 4 of DPCO, 2013:

S.No	Section	Formulations	Dosage form(s) and strength(s)	Ceiling Price	Unit
1	6.5.5	Itraconazole	Capsule 100mg	14.87	1 Capsule
2	6.5.5	Itraconazole	Capsule 200mg	19.73	1 Capsule
3	18.3.1.7	Teneligliptin	Tablet 20mg	9.89	1 Tablet
4	6.5.8	Terbinafine	Cream 1%	4.69	1 GM
5	6.2.2.2	Cefuroxime (Note 1)	Tablet 500 mg	45.87	1 Tablet
6	6.2.2.2	Cefuroxime	Injection 1500 mg	302.12	1 Vial
7	18.2.1.3	Ormeloxifene (Centchroman)	Tablet 30mg	7.53	1 Tablet
8	6.2.1.14	Meropenem	Powder for Injection 500 mg (astrihydrate)	644.82	1 Vial
9	6.2.1.14	Meropenem	Powder for Injection 1000mg (as trihydrate)	849.69	1 Vial
10	23.5.3	Nicotine (for nicotine replacement therapy)	Lozenge 2mg	7.06	1 Lozenges
11	23.5.3	Nicotine (for nicotine replacement therapy)	Gum 2 mg	7.66	1 Gum
12	23.5.3	Nicotine (for nicotine replacement therapy)	Gum 4 mg	9.49	1 Gum
13	23.5.3	Nicotine (for nicotine replacement therapy)	Lozenge 4mg	8.70	1 Lozenges
14	6.2.2.5	Clindamycin	Injection 150mg/mL	54.05	1 ML
15	10.3.4	Labetalol	Tablet 100 mg	13.52	1 Tablet
16	12.2.3	Iohexol	Injection 350mg iodine/mL	12.7	1 ML
17	18.4.2	Human chorionic gonadotropin	Injection 10000IU	827.89	1 Vial
18	18.4.2	Human chorionic gonadotropin	Injection 2000 IU	306.49	1 Vial
19	6.5.6	Mupirocin	Ointment 2%	18.1	1 GM
20	11.4.4	Salicylic acid	Ointment 3%	1.84	1 GM
21	7.1.26	Irinotecan HCl trihydrate	Solution for injection 20mg/mL	860.53	1 ML
22	19.3.8	Rota virus vaccine	As licensed	762.14	1 Vial
23	6.2.1.1	Amoxicillin	Oral liquid 125	0.91	1 ML

S.No	Section	Formulations	Dosage form(s) and strength(s)	Ceiling Price	Unit
			mg/5 mL (p)		
24	6.2.2.7	Doxycycline	Power for Injection 100 mg	448.27	1 Vial
25	11.6.1	Glycerin/glycerol (as mentioned in IP)	Topical - Lotion	1.1	1 ML
26	11.6.1	Glycerin/glycerol (as mentioned in IP)	Topical - Cream	2.11	1 GM
27	6.4.1	Amikacin	Injection 250mg/mL	48.31	1 ML

Note 1: With respect to formulation at S. No. 5 i.e., Cefuroxime tablet 500 mg, the Authority noted that inter brand variation on the same is not applicable. Hence, the ceiling price of the same may be notified under Para 4 of DPCO 2013.

Agenda item No. 6(iii): Ceiling price fixation of Atracurium Injection 10mg/ml & Dobutamine Injection 50mg/ml under NLEM,2022

- (a) The Authority deliberated upon the matter in detail and approved the ceiling price for Atracurium Injection 10mg/ml at Rs.15.14 per ML.
- (b) The Authority deliberated upon the matter in detail and approved the ceiling price for Dobutamine Injection 50mg/ml at Rs.8.05 per ML.

Agenda item No. 6(iv): Ceiling Price fixation of Insulin Glargine 100 IU/ml

The Authority noted that Insulin Glargine 100 IU/ml has been newly added under NLEM 2022. The Authority also took note of the representations made by M/s Sanofi India Ltd., USISPF and OPPI with respect to consideration of vials, cartridges and disposable pens separately stating that only that vials constitute conventional form of injection and these only should be considered as scheduled formulation. The cartridges and pens are novel drug delivery system and should not be included under ceiling unless specifically stated specifically or even if these are considered as scheduled, separate ceiling price may be fixed.

The Authority deliberated the matter in detail and decided as long as vials, cartridges and pens contain the scheduled formulation Insulin Glargine 100IU/ml, none of these (cartridge, pen, vial) can be considered outside the ceiling price as NLEM states only Insulin Glargine 100 IU /ml as a scheduled formulation. These are just different means of packaging/ delivery of the scheduled formulation.

Further, both cartridge and vial are multi dose and administered through device like injection/pen. Hence, these may not be treated as distinct. The disposable pen as claimed to be distinct from vial in terms of convenience, emergency use and better compliance and an innovative novel delivery system can be considered for separate pricing. It was also noted by the Authority that sales of vials and cartridges are around

83% of the market while disposable pens have sales of 17%. The representation of a user of insulin was also brought to the notice of the Authority who has pointed to the considerable price difference between insulin sold in vials and through other delivery systems.

After due deliberations, it was decided to fix a single ceiling price for Insulin Glargine 100IU/ml vials and cartridges at Rs.181.45 per ML under Para 4 of DPCO 2013.

The Authority also fixed the ceiling price of Insulin Glargine 100IU/ml pens at Rs.217.74 per ml for pen. This has been worked out by allowing additional 20% increase above the ceiling price of Insulin Glargine 100IU/ml vials and cartridges i.e. Rs. 181.45 per ml on account of incremental innovation/ novel drug delivery system in line with previous practice of the Authority. It was decided to notify the prices of Insulin Glargine 100IU/ml pens under Para 11 (3) of DPCO 2013.

The Authority also directed that the above ceiling prices as fixed for all formulations at points 6 (i) to 6 (iv) may be notified after applying WPI increase of 12.1218% in line with NPPA OM No. 19(119)/2022/DP/NPPA/Div.II (Vol.II) dated 27.03.2023.

7. Agenda item no. 7(i) - Agenda item no. 7-Fixation of ceiling prices of Medical Oxygen covered under National List of Essential Medicines (NLEM)

7.1 The Authority noted that Medical Oxygen as licensed for medical purpose has been included under NLEM 2022. It was noted that market data for Oxygen is not available in Pharmatrac. Letters were written to the gas manufacturing companies, their industry association (AIGMA) and government and private hospitals. No data was received from the gas manufacturing companies and AIGMA for fixation of ceiling prices. Accordingly, the fixation of ceiling prices has been done based on institutional data in line with DoP OM No. 31026/31/2016 dated 5.02.2019 under Para 19. The Authority deliberated upon the matter in detail and approved the ceiling price as below:

S.No.	Name of Drug	Unit	Ceiling Price excluding GST (Rs.)
1.	Liquid Medical Oxygen (LMO)	Cubic Meter	Rs.15.18
2.	Oxygen Inhalation (Medicinal gas) in cylinder	Cubic Meter	Rs.25.71

The Authority also directed that the above ceiling prices may be notified after applying WPI increase of 12.1218% in line with NPPA OM No. 19(119)/2022/DP/NPPA/Div.II (Vol.II) dated 27.03.2023.



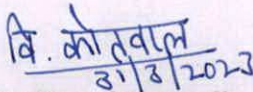
Agenda item No. 7(ii) - Fixation of ceiling prices of Nitrous oxide covered under National List of Essential Medicines (NLEM)

7.2 The Authority noted that Nitrous oxide as licensed for medical purpose has been included under NLEM 2022. It was noted that market data for Nitrous Oxide is not available in Pharmatrac. Letters were written to the gas manufacturing companies, their industry association (AIGMA) and government and private hospitals. No data was received from the gas manufacturing companies and AIGMA for fixation of ceiling prices. Accordingly, the fixation of ceiling prices has been done based on institutional data in line with DoP OM No. 31026/31/2016 dated 5.02.2019 under Para 19. The Authority deliberated upon the matter in detail and approved the ceiling price as below:

S.No.	Name of Drug	Unit	Ceiling Price excluding GST (Rs.)
1.	Nitrous Oxide	Cubic Meter	Rs.255.04

The Authority also directed that the above ceiling prices may be notified after applying WPI increase of 12.1218% in line with NPPA OM No 19(119)/2022/DP/NPPA/Div.II (Vol.II) dated 27.03.2023.

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


(Dr. Vinod Kotwal)
Member Secretary