

मिसिलस. - 8(129)/2025/डी.पी/एनपीपीए-डीवी-II

F. No. 8(129)/2025/DP/NPPA-Div. II

कार्यवाहीत. : 260/129/2025/F

Proceeding No: 260/129/2025/F

Minutes of the 261st (overall) and 129th meeting of the Authority under DPCO, 2013 held on 29.01.2025 at 01:30 pm

The 261st meeting of the Authority (overall), which is the 129th meeting under the DPCO, 2013 was held on 29th January, 2025 at 01:30 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.

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 128th Meeting held on 12.12.2024.

1.1 The minutes of the meeting were confirmed. However, the Authority was informed that there was a typographical error in the price of 'Synchrobreathe inhaler for Budesonide Inhalation (MDI) 200mcg/dose' for 200 doses in one inhaler, placed at Agenda Item No. 10 i.e. **"Application for grant of separate price/special price for 'Synchrobreathe Inhaler device' under the provision of Para 11(3) of DPCO, 2013 by M/s Cipla Ltd."** Authority noted that the correct price is Rs.81.20 per inhaler instead of Rs. 41.20 and that corrigendum in this respect shall be issued.



2. Agenda item no. 2 – Action Taken Report (ATR) on decisions taken by NPPA in its 128th Meeting held on 12.12.2024.

2.1 Noted.

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

3.1 The Authority noted the status of new drug applications and further directed to explore the possibility of simultaneously informing the applicant company about the uploading of draft worksheet on website through email/ or through the IPDMS.

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 Forty-two (42) cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (xlii) falling under the purview of Para 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of Forty-two (42) 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 Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1	4 (i)	Tranexamic Acid and Mefenamic Acid tablets	Each film coated tablet contains: Tranexamic Acid IP 500 mg Mefenamic Acid IP 250 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s Glensmith Labs Pvt. Ltd.	32.57
2	4 (ii)	Sitagliptin & Metformin Hydrochloride (Sustained Release) tablets	Each film coated bilayered tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100 mg Metformin Hydrochloride IP 500 mg (as Sustained Release)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Primus Remedies Pvt. Ltd.	12.84
3	4 (iii)	Dapagliflozin, Glimepiride, Metformin Hydrochloride (extended release) tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10 mg, Glimepiride IP 1 mg,	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s La Renon Healthcare Pvt. Ltd.	12.31

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
			Metformin Hydrochloride IP 500 mg (As Extended Release)			
4	4 (iv)	Dapagliflozin, Glimepiride, Metformin Hydrochloride (Extended Release) tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10 mg, Glimepiride IP 2 mg, Metformin Hydrochloride IP 500 mg (as Extended Release)	1 Tablet	M/s Mascot Health Series Pvt. Ltd./ M/s La Renon Healthcare Pvt. Ltd.	12.62
5	4 (v)	Glimepiride, Voglibose & Metformin Hydrochloride (SR) tablets	Each uncoated bilayered tablet contains: Glimepiride IP 0.5 mg, Voglibose IP 0.2 mg, Metformin Hydrochloride IP 500 mg (as Sustained Release form)	1 Tablet	M/s Windlas Biotech Limited/ M/s Mankind Pharma Ltd.	9.12
6	4 (vi)	Bictegravir, Emtricitabine & Tenofovir Alafenamide Tablets	Each film coated tablet contains: Bictegravir Sodium eq. to Bictegravir 50 mg, Emtricitabine IP 200 mg Tenofovir Alafenamide Fumarate IP eq. to Tenofovir Alafenamide 25 mg	1 Tablet	M/s Hetero Labs Limited / M/s Cipla Ltd.	132.58
7	4 (vii)	Glimepiride & Metformin Hydrochloride (SR) tablets	Each uncoated bilayered tablet contains: Glimepiride IP 1 mg Metformin Hydrochloride IP 1000 mg (as Sustained Release form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	9.40
8	4 (viii)	Glimepiride & Metformin Hydrochloride (SR) tablets	Each uncoated bilayered tablets contains: Glimepiride IP 3 mg, Metformin HCl IP 1000mg (Sustained Release form)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	12.03
9	4 (ix)	Glimepiride & Metformin Hydrochloride (SR) tablets	Each uncoated bilayered tablets contains: Glimepiride IP 4 mg, Metformin HCl IP 1000mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd./ M/s German Remedies	12.39

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
			(as Sustained Release form)		Pharmaceuticals Pvt. Ltd.	
10	4 (x)	Empagliflozin & Metformin Hydrochloride tablets	Each film coated tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Micro Labs Ltd.	15.84
11	4 (xi)	Empagliflozin & Metformin Hydrochloride tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 500 mg	1 Tablet	M/s Micro Labs Ltd.	18.10
12	4 (xii)	Empagliflozin & Metformin Hydrochloride tablets	Each film coated tablet contains: Empagliflozin 12.5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Micro Labs Ltd.	19.01
13	4 (xiii)	Empagliflozin & Metformin Hydrochloride tablets	Each film coated tablet contains: Empagliflozin 5 mg Metformin Hydrochloride IP 1000 mg	1 Tablet	M/s Micro Labs Ltd.	11.38
14	4 (xiv)	Linezolid for Oral Suspension	Each 5 ml of constituted suspension contains: Linezolid IP 100 mg	1 ml	M/s Pure & Cure Healthcare Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	3.86
15	4 (xv)	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 Ravenbhel Healthcare Pvt. Ltd. / M/s Corona Remedies Pvt. Ltd.	15.07
16	4 (xvi)	Telmisartan, Cilnidipine & Chlorthalidone tablets	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Chlorthalidone IP 6.25 mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd. /M/s Cadila Pharmaceuticals Ltd.	14.69
17	4 (xvii)	Telmisartan & Hydrochlorothiazide tablets	Each uncoated bilayered tablet contains: Telmisartan IP 40mg, Hydrochlorothiazide IP 12.5 mg	1 Tablet	M/s Sano-Cito Therapeutics Inc-Unit-II / M/s Zuventus Healthcare Ltd.	11.43

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
18	4 (xviii)	Atorvastatin & Ezetimibe tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 80 mg, Ezetimibe IP 10 mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd./ M/s Cadila Pharmaceuticals Ltd.	53.70
19	4 (xix)	Atorvastatin & Ezetimibe tablets	Each film coated tablet contains: Atorvastatin Calcium IP eq. to Atorvastatin 80 mg, Ezetimibe IP 10 mg	1 Tablet	M/s Windlas Biotech Ltd. / M/s Cadila Pharmaceuticals Ltd.	53.70
20	4 (xx)	Diclofenac Sodium, Paracetamol & Chlorzoxazone tablets	Each uncoated tablet contains: Diclofenac Sodium IP 50mg, Paracetamol IP 325mg Chlorzoxazone USP 250mg	1 Tablet	M/s Aagya Biotech Pvt. Ltd./ M/s Macleods Pharmaceuticals Ltd.	6.55
21	4 (xxi)	Levetiracetam tablets	Each film coated tablet contains: Levetiracetam IP 1000 mg	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	35.94
22	4 (xxii)	Clindamycin & Nicotinamide gel	Composition: Clindamycin Phosphate IP eq. to Clindamycin 1.0% w/w Nicotinamide IP 4.0% w/w	1 Gm	M/s Pilco Healthcare Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd	7.35
23	4 (xxiii)	Cefadroxil & Potassium Clavulanate dispersible tablets	Each uncoated dispersible tablet contains: Cefadroxil Monohydrate IP eq. to Anhydrous Cefadroxil 250 mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 62.5 mg	1 Tablet	M/s Innova Captab Limited / M/s Indoco Remedies Ltd.	9.72
24	4 (xxiv)	Cefadroxil & Potassium Clavulanate tablets	Each film coated tablet contains: Cefadroxil Monohydrate IP eq. to Anhydrous Cefadroxil 500 mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 125 mg	1 Tablet	M/s Innova Captab Limited / M/s Indoco Remedies Ltd.	17.61

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
25	4 (xv)	Bilastine & Montelukast Suspension	Each 5 ml suspension contains: Bilastine IP 10 mg Montelukast Sodium IP eq. To Montelukast 4mg	1 ml	M/s Synokem Pharmaceuticals Limited / M/s Intas Pharmaceuticals Limited	1.69
26	4 (xxvi)	Amoxycillin & Potassium Clavulanate Oral Suspension	Each 5 ml of reconstituted suspension contains: Amoxycillin Trihydrate IP eq. to Amoxycillin 600 mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9 mg	1 ml	M/s Malik Lifesciences Pvt. Ltd./ M/s Aurobindo Pharma Ltd.	2.68
27	4 (xxvii)	Aspirin gastro-resistant & Atorvastatin capsules	Each hard gelatin capsule Contain: Aspirin IP 75 mg (as gastro-resistant tablet IP) Atorvastatin Calcium IP eq. to Atorvastatin 40 mg	1 Capsule	M/s Windlas Biotech Ltd. / M/s Intas Pharmaceuticals Ltd.	18.27
28	4 (xxviii)	Bisoprolol Fumarate and Amlodipine Besilate tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5 mg Amlodipine besilate IP eq. to Amlodipine 5 mg	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	6.26
29	4 (xxix)	Paracetamol, Phenylephrine Hydrochloride & Chlorpheniramine Maleate Tablets	Each uncoated tablet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 10mg Chlorpheniramine Maleate IP 2 mg	1 Tablet	M/s East African (India) Overseas /M/s Medley Pharmaceuticals Ltd.	4.81
30	4 (xxx)	Paracetamol, Phenylephrine Hydrochloride, Caffeine & Diphenhydramine HCl tablets	Each uncoated tablet contains: Paracetamol IP 500mg Phenylephrine Hydrochloride IP 5 mg Diphenhydramine HCl IP 25 mg Caffeine IP (anhydrous) 30 mg	1 Tablet	M/s Juggat Pharma (Pharma Division of Jagdale Industries Pvt. Ltd.)	4.22
31	4 (xxxi)	Paracetamol & Mefenamic Acid Suspension	Each 5 ml contains: Paracetamol IP 250 mg Mefenamic Acid IP 100 mg	1 ml	M/s Yacca Lifesciences Pvt. Ltd./ M/s Intas	0.88

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
					Pharmaceuticals Ltd.	
32	4 (xxxii)	Mefenamic Acid & Paracetamol Suspension	Each 5 ml contains: Mefenamic Acid IP 100 mg Paracetamol IP 250 mg	1 ml	M/s Shiva Biogenetic Pharmaceuticals Pvt. Ltd. /M/s Aristo Laboratories Pvt. Ltd.	0.88
33	4 (xxxiii)	Mefenamic Acid & Paracetamol Suspension	Each 5 ml contains: Mefenamic Acid IP 50 mg Paracetamol IP 125 mg	1 ml	M/s Shiva Biogenetic Pharmaceuticals Pvt. Ltd. /M/s Aristo Laboratories Pvt. Ltd.	0.73
34	4(xxxiv)	Paracetamol & Polmacoxib tablets	Each uncoated tablet contains: Paracetamol IP 325 mg Polmacoxib IH 2 mg	1 Tablet	M/s Hetero Labs Ltd./ M/s Micro Labs Ltd.	15.26
35	4(xxxv)	Paracetamol & Polmacoxib tablets	Each uncoated tablet contains: Paracetamol IP 325 mg Polmacoxib IH 2 mg	1 Tablet	M/s Hetero Labs Ltd./ M/s Abbott Healthcare Pvt. Ltd.	15.26
36	4(xxxvi)	Paracetamol & Polmacoxib tablets	Each uncoated tablet contains: Paracetamol IP 325 mg Polmacoxib IH 2 mg	1 Tablet	M/s Hetero Labs Limited/ M/s Mankind Pharma Ltd.	15.26
37	4(xxxvii)	Polmacoxib and Paracetamol tablets	Each uncoated tablet contains: Paracetamol IP 325 mg Polmacoxib IH 2 mg	1 Tablet	M/s Hetero Labs Limited / M/s Torrent Pharmaceuticals Ltd.	15.26
38	4(xxxviii)	Bisoprolol Fumarate and Amlodipine besilate tables	Each film coated tablet contains: Bisoprolol Fumarate IP 5 mg Amlodipine besilate IP eq. to Amlodipine 5 mg	1 Tablet	M/s Macleods Pharmaceuticals Ltd.	8.54
39	4(xxxix)	Cetirizine Drops	Each ml contains: Cetirizine Hydrochloride IP 10 mg	1 ml	M/s Zuventus Healthcare Ltd.	7.78

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)	(7)
40	4(xl)	Telmisartan, Cilnidipine & Chlorthalidone tablets	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10 mg Chlorthalidone IP 6.25 mg	1 Tablet	M/s Skymap Pharmaceuticals Pvt. Ltd. /M/s German Remedies Pharmaceuticals Pvt. Ltd.	14.92
41	4(xli)	Atorvastatin, Clopidogrel & Aspirin Capsules	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 10 mg (As Pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg (As Pellets) Aspirin IP 75 mg (as enteric coated Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Ipca Laboratories Ltd.	5.75
42	4(xlii)	Atorvastatin, Clopidogrel & Aspirin Capsules	Each hard gelatin capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 20 mg (As Pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg (As Pellets) Aspirin IP 75 mg (as enteric coated Pellets)	1 Capsule	M/s Synokem Pharmaceuticals Ltd. / M/s Ipca Laboratories Ltd.	7.95

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

5.1 Noted.

6. Agenda item no. 6: Revision of retail price based on Review Orders.

6.1 The Authority noted that the DoP has passed review order no. 31015/60/2023-Pricing dated 04.10.2024 in relation to retail price fixation of "**Cilnidipine + Telmisartan 20+40mg tablet**" for M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited notified vide S.O. No. 1434(E) dated 27.03.2023 at Rs.12.83 per tablet.

6.2 It was noted that M/s Glenmark Pharmaceuticals Limited filed a review application for correction of price-to-retailer (PTR) as considered for the brand 'CINOD T 20/40' manufactured/ marketed by M/s Ajanta Pharma Limited from Rs.148.57 for pack of 15 tablets to Rs.200.

6.3 The Authority further noted that in the review hearing, NPPA was directed to get confirmation w.r.t. PTR and MRP of this product from M/S Ajanta Pharma Ltd. as well as from the Pharmarack. It has been found that M/S Ajanta Pharma Ltd. has not filed the Form V. Further, M/s Pharmarack informed that there was some technical glitch in their data base, which they had identified and corrected and they confirmed the PTR of pack of 15 tablets at Rs.200 and MRP at Rs.280. The above was informed to the DoP. Accordingly, DoP referred back the matter to NPPA for re-calculation.

6.4 The Authority also noted that revised draft working sheet with retail price calculated at Rs. 14.15 per tablet considering the revised PTR at Rs.200 per 15 tablets was uploaded on website on 29.11.2024 and no representation has been received.

6.5 In view of the above, the Authority deliberated upon the matter and approved revised retail prices for M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited for the formulation **Each film coated tablet contains: Cilnidipine IP 20mg Telmisartan IP 40mg** at Rs. 14.15 per tablet.

7. Agenda item no. 7: Revision of ceiling prices based on Review Orders under NLEM, 2022

7.1 The Authority noted the following review orders issued by Department of Pharmaceuticals (DoP):

Table 2: Review Orders of DoP

S. No.	Date & No. of Review Order	Formulation and Notification
1.	Order no. 31015/43/2023- Pricing dated 04.10.2024	'Azithromycin 250mg tablet' of M/s Cipla Limited against NPPA notification S.O No. 484(E) dated 02.02.2023
2.	Order no. 31015/34/2023- Pricing dated 04.10.2024	'Amoxycillin 1000mg + Clavulanic acid 200mg Powder for injection' of M/s Cipla Limited against NPPA notification S.O No. 87(E) dated 06.01.2023

7.2 The Authority noted that in case of review order at S. No 1 above, DoP referred back the case to NPPA as M/s Cipla Ltd filed review petition claiming that their product 'Azee 250mg tablet 6's' was not considered in the ceiling price calculation. The matter was examined and clarification was sought from Pharmarack which clarified that as per their data base relevant SKU was discontinued in October, 2019, hence the value is zero in dataset. But on analysis from the data sources they found that the SKU was relaunched in the month of March, 2021. Accordingly, they provided the final data. Based on the data provided, revised draft work sheet was uploaded on website on 08.01.2025 *by including the brand "Azee 250mg tablet 6's"* of M/s Cipla Ltd. with PTR at Rs. 9.38 per tablet. The revised price was calculated at Rs.11.67 per tablet after giving effect of WPI increase of 12.1218% w.e.f. 1.04.2023 and WPI increase of (+)0.00551% w.e.f. 01.04.2024 as against

the previous notified price of Rs.10.39 per tablet. It was noted that no representation has been received.

7.3 In case of review order at S. No. 2, DoP referred back the case to NPPA as M/S Cipla filed review application for consideration of correct PTR for their brand 'Advent 1.2 gm powder for injection' at Rs.111.52 per vial instead of Rs.100.69 as considered by NPPA in the calculation of ceiling price. DoP directed NPPA to relook into the issue and examine with respect to pack size available in Pharmarack and contention of the Applicant regarding pack size. Accordingly, confirmation was sought from Pharmarack wherein Pharmarack confirmed that correct pack size of 'Advent 1.2' is 20 ml. The PTR claimed by the company was verified with Form II filed by the company for the said brand and pack size. The revised price was calculated at Rs.141.65 per vial after giving effect of WPI increase of 12.1218% w.e.f. 1.04.2023 and WPI increase of (+)0.00551% w.e.f. 01.04.2024 as against the previous notified price of Rs.125.44 per vial. It was noted that no representation has been received.

7.4 The Authority deliberated upon the matter in detail and approved the ceiling prices as mentioned in Column 5 of Table 3.

Table 3: Revision in Ceiling Prices based on Review Orders

S. No.	Formulation	Dosage form(s) and strength(s)	Current Ceiling Price (in Rs.)	Revised Ceiling Price (in Rs.) [based on Review orders]	Unit
1	2	3	4	5	6
1.	Azithromycin	Tablet 250 mg	11.65	11.67	1 Tablet
2.	Amoxicillin (A) + Clavulanic acid (B)	Powder for Injection 1 g (A) +200mg (B)	140.66	141.65	1 vial

8. Agenda item no. 8: Retail price fixation of drugs under Phase IV clinical trial and Category 'd' as per Kokate Committee.

8.1 The Authority recalled that the matter related to retail price fixation of drugs under Phase IV clinical trial and category 'd' drugs as per Kokate Committee was placed before the Authority in 106th meeting held on 30.12.2022 wherein it was decided that "... since the drug is already approved by SLA and has to be in market, the retail price may be fixed by NPPA based on the copy of application submitted to DCGI for conducting Phase IV clinical trials/ NOC issued by DCGI/license issued by DCGI along with the Form 1. Accordingly, applications were being processed.

8.2 Authority was informed that in the recent past NPPA has received form I applications where the applicants have made application to O/o DCGI for phase IV trial in the year 2016,2021, 2022 etc. and even after the lapse of considerable time they have

not received approval/ NOC from the O/o DCGI. Further, in one of case, company received NOC from O/o DCGI in 2018 and did not conduct the trials in the period of one year as required in the NOC. The matter was examined in consultation with CDSCO and it has been observed that despite lapse of substantial time since the application were made to CDSCO:

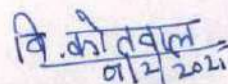
- i. Either the companies have not submitted active post marketing surveillance (PMS) data to the CDSCO; or
- ii. queries raised by the CDSCO have not been responded by the companies; or
- iii. Information on conduct of active Post Marketing Surveillance is yet to be submitted to the CDSCO.

8.3 The representative from the O/o DCGI informed that the approval of the protocol by the DCGI is a must before launch of category D drug in the market. The Authority deliberated upon the matter and accordingly, it was decided that in case of drugs under Phase IV clinical trial or category 'd' drugs, retail prices may be fixed on the basis of permission issued for conducting phase IV trail and in case of drugs under Post Marketing surveillance, retail price may be fixed based on NoC issued by O/o DCGI. The validity of the Phase-IV clinical trial is two years.

9. Agenda item no. 9: Minutes of 64th meeting of Multidisciplinary Committee of Experts held on 06.12.2024.

9.1 Noted.

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


(Dr. Vinod Kotwal)
Member Secretary