

मिसिलस.- 8(123)/2024/डी.पी/एनपीपीए-डीवी-II
F. No. 8(123)/2024/DP/NPPA-Div. II

कार्यवाहीस. : 255/123/2024/F
Proceeding No: 255/123/2024/F

Minutes of the 255th(overall) and 123rdmeeting of the Authority under DPCO, 2013 held on 10.05.2024 at 03:30 PM.

The 255thmeeting of the Authority (overall), which is the 123rd meeting under the DPCO, 2013 was held on 10th May, 2024 at 03:30PM 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
- (iii) Shri Antony Cyriac, Economic Advisor, Department of Economic Affairs

Shri Ranga Chandrashekar, Deputy Drug Controller, CDSCO, Ministry of Health & Family Welfare was also present.

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

- (i) Shri Sanjay Kumar, Advisor (Cost)
- (ii) Shri G.L. Gupta, Director (M&E)
- (iii) Ms. Rashmi Tahiliani, Director (Pricing)
- (iv) Shri. Mahaveer Saini, Deputy Director (Pricing)
- (v) Shri Rajesh Kumar T, Deputy Director (M&E)
- (vi) Ms. Yuvika Panwar, Assistant Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 122ndMeeting held on 20.03.2024.

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 122ndMeeting held on 20.03.2024.

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 following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (xxxvii) (total 41 Form I applications containing retail price fixation of 41 new drug) falling under the purview of Para 2(1) (u) of DPCO, 2013 and approved the retail prices of 41(Forty-one) new drugs under Para 5 and 15 of the DPCO 2013 as given below in **Table 1& Table 2:**

Table No. 1: Retail price fixation of new drugs

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (i) a	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s La Renon Healthcare Pvt. Ltd.	14.75 (Note 1)
4 (i) b	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	14.53
4 (i) c	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	14.75
4 (ii) a	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s La Renon Healthcare Pvt. Ltd.	16.00

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (ii) b	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	16.24
4 (ii) c	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Extended release) Glimepiride IP 2 mg	1 Tablet	M/s Akums Drugs and Pharmaceuticals Ltd. / M/s Abbott Healthcare Pvt. Ltd.	16.43
4 (xxviii)	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	13.35
4 (xxix)	Sitagliptin Phosphate, Metformin Hydrochloride and Glimepiride Tablets	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	15.03
4 (xxx)	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended release) Glimepiride IP 1 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	13.24
4 (xxxi)	Dapagliflozin, Metformin Hydrochloride (Extended Release) and Glimepiride Tablets	Each film coated bilayered tablet contains: Dapagliflozin Propanediol USP eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Extended	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Primus Remedies Pvt. Ltd.	14.83

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		release) Glimepiride IP 2 mg			
4 (iii)	Diclofenac Diethylamine, Methyl Salicylate, Virgin Linseed Oil & Menthol Topical spray	Composition: Diclofenac Diethylamine IP 1.16% w/w eq. to Diclofenac Sodium 1.00% w/w, Methyl Salicylate IP 10.00% w/w, Virgin Linseed Oil BP 3.0% w/w, Menthol IP 5.00% w/w	1 gm	M/s Pontika Aerotech Limited / M/s Unison Pharmaceuticals Pvt. Ltd.	2.73
4 (iv)	Povidone-Iodine Ornidazole Ointment	Composition: Povidone-Iodine IP 5%w/w (Available Iodine 0.5%w/w) Ornidazole IP 1% w/w in an Ointment base	1 gm	M/s Curetech Skincare / M/s J.B. Chemicals & Pharmaceuticals Ltd.	4.11
4 (v)	Bisoprolol Fumarate and Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5 mg Telmisartan IP 40 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt Ltd / M/s J.B. Chemicals & Pharmaceuticals Ltd.	11.21
4 (vi)	Bisoprolol Fumarate and Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5 mg Telmisartan IP 40 mg	1 Tablet	M/s Ravenbhel Healthcare Pvt Ltd / M/s J.B. Chemicals & Pharmaceuticals Ltd.	9.65
4 (vii)	Cefixime and Ofloxacin Oral suspension	Each 5ml reconstituted suspension contains: Cefixime IP as trihydrate eq. to Cefixime Anhydrous 50mg Ofloxacin IP 50mg	1 ml	M/s Innova Captab Ltd. / M/s Emcure Pharmaceuticals Ltd.	1.90
4 (viii)	Ibuprofen & Paracetamol Tablets	Each uncoated tablet contains: Ibuprofen IP 400mg Paracetamol IP 325mg	1 Tablet	M/s Prochem Pharmaceuticals Pvt. Ltd. / M/s Softdeal Pharmaceuticals Private Limited	1.59
4 (ix)	Ranitidine Hydrochloride, Dicyclomine Hydrochloride &	Each film coated tablet contains: Ranitidine Hydrochloride IP eq. to Ranitidine 150mg	1 Tablet	M/s Indoco Remedies Limited	2.09 (Note 2)

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Activated Simethicone Tablet	Dicyclomine Hydrochloride IP 10mg Activated Dimethicone IP (Simethicone) 20mg			
4 (x)	Telmisartan, Amlodipine & Hydrochlorothiazide Tablets	Each film coated Tablet contains: Telmisartan IP 80mg, Amlodipine Besilate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.50mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	15.96
4 (xi)	Telmisartan, Amlodipine & Hydrochlorothiazide Tablets	Each film coated Tablet contains: Telmisartan IP 40mg, Amlodipine Besilate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.50mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Torrent Pharmaceuticals Ltd.	10.45
4 (xii)	Ceftazidime and Avibactam powder for concentrate for solution for infusion	Each vial contains: Ceftazidime Pentahydrate (Sterile) eq. to Ceftazidime 2.0gm Avibactam Sodium (Sterile) eq. to Avibactam 0.5gm Sodium per vial content 6.44 mmol eq. to 148mg	1 Vial	M/s Aqua Vitoe Laboratories / M/s Emcure Pharmaceuticals Limited	1569.94
4 (xiv)	Glimepiride & Metformin Hydrochloride (ER) tablets	Each uncoated bilayered tablet contains: Glimepiride IP 4mg Metformin Hydrochloride IP 500mg (In extended-release form)	1 Tablet	M/s Innova Captab Ltd. / M/s Cadila Pharmaceuticals Ltd.	11.28
4 (xv)	Glimepiride & Metformin Hydrochloride (ER) tablets	Each uncoated bilayered tablet contains: Glimepiride IP 3mg Metformin Hydrochloride IP 500mg (In extended-release form)	1 Tablet	M/s Innova Captab Ltd. / M/s Cadila Pharmaceuticals Ltd.	9.84
4 (xvi)	Bilastine and Montelukast oral suspension	Each 5ml suspension contains: Bilastine 10mg	1 ml	M/s Akums Drugs & Pharmaceuticals	1.72

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Montelukast Sodium IP eq. to Montelukast 4mg		Ltd. / M/s Sun Pharmaceuticals Industries Limited	
4 (xvii)	Aceclofenac, Paracetamol & Thiocolchicoside Tablets	Each film coated tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg Thiocolchicoside IP 8mg	1 Tablet	M/s Innova Captab Ltd. / M/s Mankind Pharma Ltd.	25.98
4 (xviii)	Aceclofenac, Paracetamol & Thiocolchicoside Tablets	Each film coated tablet contains: Aceclofenac IP 100mg Paracetamol IP 325mg Thiocolchicoside IP 4mg	1 Tablet	M/s Innova Captab Ltd. / M/s Mankind Pharma Ltd.	18.05
4 (xix)	Hydrocortisone Acetate, Lidocaine, Zinc Oxide & Allantoin Suppositories	Each suppository contains: Hydrocortisone Acetate IP 0.25% w/w Lidocaine USP 3.0% w/w Zinc Oxide IP 5.0% w/w Allantoin IP 0.5% w/w	1 Suppository	M/s Bliss GVS Pharma Ltd. / M/s Zyduz Healthcare Limited	14.30
4 (xx)	Ciprofloxacin & Tinidazole Tablet	Each film coated tablet contains: Ciprofloxacin Hydrochloride IP eq. to Ciprofloxacin 500mg Tinidazole IP 600mg	1 Tablet	M/s Aagya Biotech / M/s J. B. Chemicals & Pharmaceuticals Ltd.	10.64
4 (xxi)	Fexofenadine Hydrochloride & Montelukast Tablet	Each film coated tablet contains: Fexofenadine Hydrochloride IP 120mg Montelukast Sodium IP eq. to Montelukast 10mg	1 Tablet	M/s Aagya Biotech / M/s J. B. Chemicals & Pharmaceuticals Ltd.	15.10
4 (xxii)	Antacid Anti-gas gel	Each 10ml contains: Dried Aluminium Hydroxide Gel IP (added as paste) 830mg Magnesium Hydroxide IP (added as paste) 185mg Sodium Carboxy methyl cellulose IP	1 ml	M/s Intas Pharmaceuticals Pvt. Ltd.	0.56

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		100mg Simethicone IP 50mg			
4 (xxiii)	Bisoprolol Fumarate and Amlodipine Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s Savi Health Science / M/s Alkem Laboratories Ltd.	6.40
4 (xxiv)	Bisoprolol Fumarate and Amlodipine Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s Savi Health Science / M/s Alkem Laboratories Ltd.	8.98
4 (xxv)	Atorvastatin, Clopidogrel & Aspirin Capsule	Each hard gelatine capsule contains: Atorvastatin Calcium IP eq. to Atorvastatin 40mg (As green coloured pellets), Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two reddish brown coloured film coated tablet, each containing 37.5mg Clopidogrel Tablets IP), Aspirin IP 75mg (As enteric coated white-coloured pellets)	1 Capsule	M/s Windlas Biotech Limited / M/s Aristo Pharmaceuticals Pvt. Ltd.	13.84
4 (xxvi)	Levocetirizine Dihydrochloride & Montelukast Sodium suspension	Each 5ml contains: Levocetirizine Dihydrochloride IP 2.5mg Montelukast Sodium IP eq. to Montelukast 4mg	1 ml	M/s Aagya Biotech / M/s J. B. Chemicals & Pharmaceuticals Ltd.	1.47
4 (xxvii)	Linagliptin & Metformin Hydrochloride (ER) Tablets	Each film coated bilayered Tablet contains: Linagliptin 5mg Metformin Hydrochloride IP 500mg (as extended release form)	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Mankind Pharma Limited	12.86
4 (xxxii)	Pantoprazole & Domperidone Tablet	Each gastro-resistant tablet contains: Pantoprazole Sodium IP (as sesquihydrate)	1 Tablet	M/s Innova Captab Ltd. / Dr. Reddy's	7.24

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		eq. to Pantoprazole 40mg Domperidone IP 10mg		Laboratories Limited	
4 (xxxiii)	Chlorpheniramine Maleate, Dextromethorphan & Phenylephrine Syrup	Each 5ml contains: Chlorpheniramine Maleate IP 2mg Phenylephrine Hydrochloride IP 5mg Dextromethorphan Hydrochloride IP 10mg	1 ml	M/s Stedman Pharmaceuticals Pvt. Ltd.	1.02
4 (xxxiv)	Cefixime and Ofloxacin Oral suspension	Each 5ml reconstituted suspension contains: Cefixime IP as trihydrate eq. to Cefixime Anhydrous 50mg Ofloxacin IP 50mg	1 ml	M/s Innova Captab Ltd. / Dr. Reddy's Laboratories Limited	1.90

Note 1: The Authority noted that for the formulation "Metformin (1000mg) (as Extended release) + Glimepiride (1mg)", there is typographical error in the SKUs & brand name at S.No. 54 to S.No. 73 of the Draft worksheet. However, the PTR, packsize, MAT & the market share is correctly captured. Hence, there would be no impact on the qualifying PTR and the worked out price. The Authority, therefore, directed to upload corrected worksheet on the Website.

Note 2: The Authority noted that the company represented against the draft working sheet uploaded on NPPA website stating that the worked-out price is very low and that only one SKU is considered in draft working sheet, with negligible sales. The Authority further noted that the retail prices are fixed based on the available market-based data and in this case, data of only one SKU is reflected in the database. Further, Pharmatrac has reconfirmed the data. Accordingly, the Authority decided that the representation of company may not be accepted.

4.2 It was noted by the Authority that in the following four cases the companies have launched the formulations without obtaining price approval from NPPA. The Authority deliberated upon the worked out price, claimed price and the launch price and approved the lowest of the three prices as the retail price of the new drugs as given below:

Table No. 2: Retail price fixation of new drugs

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (xiii)	Ceftazidime and Avibactam powder for concentrate for solution for infusion	Each vial contains: Ceftazidime Pentahydrate IP eq. to Ceftazidime 2.0gm Avibactam Sodium eq. to Avibactam 0.5gm	1 Vial	M/s Protech Telelinks / M/s Samarth Life Sciences Pvt. Ltd.	2074.74

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (xxxv)	Vitamin D3 Oral Solution	Each 5ml contains: Cholecalciferol IP 600000 IU (In Nano Droplet form)	1ml	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s La Renon Healthcare Pvt. Ltd.	11.63
4 (xxxvi)	Telmisartan and Chlorthalidone Tablet	Each film coated tablet contains: Telmisartan IP 40mg Chlorthalidone IP 12.50mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s La Renon Healthcare Pvt. Ltd.	7.39
4 (xxxvii)	Telmisartan and Amlodipine Tablet	Each uncoated bilayered tablet contains: Telmisartan IP 80mg Amlodipine Besilate IP eq. Amlodipine 5mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s La Renon Healthcare Pvt. Ltd.	13.21

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

5.1 Noted

6. Agenda item no. 6 –Revision of ceiling prices based on review order.

6.1 The Authority noted that NPPA has received Review Order No. 31015/75//2023 -Pricing (E-24296) dated 05.03.2024 filed by M/s Macleods Pharmaceuticals in relation to fixation of ceiling price of **Isoniazid 100 mg Tablet at Rs 0.65 per tablet** notified vide SO No. 2540 (E) dated 08.06.2023 issued by the Department of Pharmaceuticals (DoP). In the review order, it was directed to review the PTR of M/s Macleods Pharmaceuticals. The draft calculation sheet with revised ceiling prices was uploaded on NPPA website on 15.03.2024 for comments. The Authority noted that no representations have been received

6.2 The Authority also noted that the revised ceiling price comes to Rs. 0.73 per tablet. It was further observed that, the ceiling price based on WPI increase of (+) 0.00551% w.e.f. 01.04.2024 is also Rs. 0.73 per tablet. Accordingly, the Authority approved the revised ceiling price with WPI effect at Rs. 0.73 per tablet.

7. Agenda item no. 7 –Revision of ceiling price of FORMOTERAL 6MCG + BUDESONIDE 400MCG (DPI) as per the framework for undertaking suo-moto correction by NPPA.

7.1 The Authority noted that matter related to the ceiling price of FORMOTERAL 6MCG + BUDESONIDE 400MCG (DPI) was approved in 121st meeting held on 20.02.2024 and was notified vide S.O. No. 938(E) dated 28.02.2024 at Rs. 6.62 per dose. However, after the notification, representations were received from 3 companies viz. M/s Zydus Healthcare Ltd, M/s Glenmark and M/s Mankind Pharma stating that Mankind's MDI was

included in the calculation of DPI and request was also received for suo-moto correction by NPPA as per the framework approved in 105th Authority meeting. M/s Mankind Pharma Limited stated that it had only 2 SKUs: one MDI and other DPI.

7.2 The Authority was informed that that M/s Mankind had earlier based on the draft worksheet uploaded on the web-site on 05.02.2024 represented that one of its DPI SKU has been wrongly reported in MDI and needs to be considered in DPI and also requested for correction in the pack size of the same. After considering the same, the ceiling price was approved at Rs. 6.62 per dose in the 121st Authority meeting held on 20.02.2024.

7.3 However, a representation was received from M/s Mankind after the notification (as referred in Para 7.1. Hence, confirmation/ clarification was sought from both M/s Mankind Pharma Limited and Pharmatrac to provide complete details of products sold for both MDI and DPI formulations. Pharmatrac provided the details of 3 SKUs of which 2 SKUs are DPI formulation sold by M/s Mankind. Pharmatrac, however, revised the pack size from 400 to 30 and PTR of COMBIHALE FB 6/400 MCG INHALER 400 DPI to Rs. 154.47. Further, M/s Mankind Pharma clarified that there is only one product of DPI formulation marketed by them as on date. The company further stated that earlier the same product was marketed by Dr. Reddy Labs and was acquired by them in February 2022.

7.4 Since M/S Mankind Pharma Limited gave conflicting statements about their product, in two different representations, the price was worked out based on confirmation from M/S Pharmatrac and ceiling price was uploaded on website on 28.03.2024 at Rs.6.95 per dose.

7.5 The Authority further recalled the decision taken in 105th meeting held on 15.12.2022 wherein it was decided that NPPA may carry out suo moto correction even after notification where errors are duly acknowledged by Pharmatrac and /or correct data is confirmed from the companies.

7.6 Further, the Authority also rejected the representation that this SKU should not be considered as it has been discontinued and has low market share. Authority noted since, the SKU is appearing in October 2023 database, the same has been considered in calculation of ceiling price by adding two SKUs with same brand name in line with practice followed.

7.7 The Authority also noted that M/s Cipla Limited had withdrawn the review application on 05.04.2024 filed against NPPA's notification S.O. No.938 (E) dated 28.02.2024 in respect of the subject formulation. Further, NPPA vide letter dated 22.04.2024 had informed DoP about the revised draft sheet uploaded on website and to pursue the ceiling price revision under suo-moto correction.

7.8 The matter was deliberated in detail, and in view of above it was decided to revise the ceiling price of FORMOTERAL 6MCG + BUDESONIDE 400MCG (DPI) to Rs. 6.95 per dose. The Authority further decided that the revised ceiling may further be notified at Rs. 6.95 per dose after considering the impact of WPI revision @+0.00551% effective from 01.04.2024.

8. Agenda item no. 8 –Retail price fixation of new drugs with M/s Synokem Pharmaceuticals Limited as the manufacturer.

8.1 The Authority noted that NPPA has received eleven (11) Form I applications for retail price approval of new drugs with M/s Synokem Pharmaceuticals Limited, as the manufacturer which were deferred in 122nd Authority meeting held on 20.03.2024 as it was learnt that the Drug Control Authorities have suspended/ cancelled the licenses issued in the name of M/s Synokem Pharmaceuticals Limited and clarification is sought from office of DCGI and State Licensing Authority (SLA) in this regard.

8.2 The Authority noted that the State Licensing Authority of Uttarakhand, vide letter dated 18.03.2024 (received on 26.03.2024), informed NPPA that the drug manufacturing license of the firm M/s Synokem Pharmaceuticals Ltd., Plot No. 35-36, Sidcul, District Haridwar, Uttarakhand is valid as on date, however, an order of Stop Production bearing order no. 17P/1/37/2005/608 dated 23/02/2024 has been issued for Tablets, Capsules and Oral liquid section of general category of the firm, in view of violation of GMP & GLP norms as observed during joint inspection dated 16/02/2024.

8.3 The matter was deliberated in the Authority meeting and based on above clarification, it was decided that form I applications of following companies may be rejected and the companies may file fresh form I application when M/s Synokem Pharmaceuticals Ltd., Plot No. 35-36, Sidcul, District Haridwar, Uttarakhand is allowed to start production of the applied formulations:

S.No.	Name of the Formulation / Brand Name	Manufacturer & Marketing Company	Date of Application
(1)	(2)	(3)	(4)
1	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 500mg	M/s Synokem Pharmaceuticals Limited / M/s Aristo Pharmaceuticals Pvt. Ltd.	05.12.2023 (Complete application on 26.12.2023)
2	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Vildagliptin (As Sustained release) IP 100mg Metformin Hydrochloride (as Sustained Release) IP 1000mg	M/s Synokem Pharmaceuticals Limited / M/s Aristo Pharmaceuticals Pvt. Ltd.	05.12.2023 (Complete application on 26.12.2023)
3	Each film coated tablet contains: Telmisartan IP 40 mg Cilnidipine IP 10mg	M/s Synokem Pharmaceuticals Ltd. / M/s Emcure Pharmaceuticals Limited	31.01.2024
4	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg	M/s Synokem Pharmaceuticals Limited / M/s Primus Remedies Pvt. Ltd.	02.02.2024 (Complete application)

S.No.	Name of the Formulation / Brand Name	Manufacturer & Marketing Company	Date of Application
(1)	(2)	(3)	(4)
	Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 500mg (extended release)		date 26.02.2024)
5	Each film coated bilayered tablet contains: Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 100mg Metformin Hydrochloride IP 1000mg (extended release)	M/s Synokem Pharmaceuticals Limited / M/s Primus Remedies Pvt. Ltd.	02.02.2024 (Complete application date 26.02.2024)
6	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	M/s Synokem Pharmaceuticals Ltd. / M/s Macleods Pharmaceuticals Limited	22.01.2024 (Complete Date 01.02.2024)
7	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	M/s Synokem Pharmaceuticals Ltd. / M/s Macleods Pharmaceuticals Limited	22.01.2024 (Complete Date 01.02.2024)
8	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1 mg	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Limited	19.02.2024
9	Each film coated tablet contains: Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2 mg	M/s Synokem Pharmaceuticals Ltd. / M/s Aristo Pharmaceuticals Limited	19.02.2024
10	Each film coated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 500mg (As Sustained Release)	M/s Synokem Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	25.10.2023 (Complete application on 21.11.2023)
11	Each film coated bilayer tablet contains: Teneligliptin Hydrobromide Hydrate IP eq. to Teneligliptin 20mg Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg Metformin Hydrochloride IP 1000mg (As Sustained Release)	M/s Synokem Pharmaceuticals Ltd. / M/s Glenmark Pharmaceuticals Limited	25.10.2023 (Complete application on 21.11.2023)

9. Agenda item no. 9 - Form-IV intimation by M/s GlaxoSmithKline Pharmaceuticals Limited (GSK) for discontinuation of the scheduled formulation viz., Grisovin FP 250mg Tablet containing Griseofulvin under Para 21(2) of DPCO, 2013.

9.1 The Authority deliberated upon the matter in detail and decided to invoke Para 3 of DPCO, 2013 to direct M/s GlaxoSmithKline Pharmaceutical Limited to continue the production and sales of Griseofulvin 250 mg Tablet upto 31.05.2025 and to ensure that the production is not reduced by more than 25% of the normal production level i.e production level before filing of Form IV intimation.

10. Agenda item no. 10 - Fixation of ceiling prices of 7 formulation uploaded on 08.04.2024 under NLEM,2022

10.1 The Authority noted that ceiling price of 733 formulations have been fixed under NLEM 2022 based on the methodology for fixation of ceiling price of scheduled formulations under revised Schedule-I (NLEM, 2022) that was deliberated in the 104th, 111th and 112th meeting of the Authority held on 23.11.2022, 29.03.2023 and 01.05.2023 respectively. Further, the Authority also recalled the decision taken in 120th meeting held on 24.01.2024 wherein it was decided to use October 2023 database and the month of October, 2023 for fixation of the ceiling prices of remaining formulations under NLEM, 2022 under para 9 (7) of DPCO, 2013.

10.2 The Authority noted that based on approved methodology, ceiling prices for 07 formulations were uploaded on NPPA website on 08.04.2024 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 based on database of October 2023 & month of October 2023. Further, the effect of WPI for 2024 i.e. (+) 0.00551% (effective from 01.04.2024) has also been given in the draft uploaded worksheet

10.3 The Authority noted that claims/representations were received for correction in PTR. The same have been cross verified with the Form-II/Form-V submitted by the companies till 15.05.2023 as per provisions of DPCO, 2013.

10.4 The Authority noted that in respect of Cloxacillin Capsule 500mg and Capsule 250mg, the prices are proposed under para 6 (2) of DPCO 2013 and monopoly restriction under para 6 (1) has not been applied.

10.5 The Authority recalled that draft ceiling price of Oxaliplatin Injection 5mg/ml in 20ml pack, was earlier uploaded on 02.02.2023 & representations were placed in 109th meeting of Authority held on 21.02.2023. However, the same was deferred and Authority had directed to recheck & confirm the data for all the line items of Oxaliplatin. Accordingly, the Authority was informed that data was sought from Pharmatrac. Pharmatrac has intimated about the change in pack sizes of several line items. Accordingly, the draft ceiling price based on the data revised by Pharmatrac was

uploaded. Further, no representation has been received against the draft worksheet uploaded.

10.5 The Authority was informed that representations have been received in respect of Pneumococcal vaccine which needs to be further examined. Accordingly, it was decided to defer the ceiling price fixation of Pneumococcal vaccine.

10.4 The Authority deliberated upon matter and approved the ceiling prices of 06 scheduled formulations as mentioned in **Table 3** below-

Table3: Ceiling Price fixation

S.NO.	Section	Formulations	Dosage form(s) and strength(s)	Prevailing Ceiling	New Ceiling Price	Unit
(1)	(2)	(3)	(4)	(5)	(7)	(8)
1	6	Ampicillin	Powder for injection 1000 mg	26.56	24.92	1 Vial
2	6	Cloxacillin	Capsule 500mg	2.38	2.38	1 Capsule
3	6	Cloxacillin	Capsule 250mg	1.41	1.41	1 Capsule
4	7	Oxaliplatin	Injection 5 mg/mL in 20ml vial	5563.91	4979.68	1 Vial
5	17	Oral Rehydration Salts	As licensed (Powder)	1.11	0.99	1 GM
6	17	5-Amino Salicylic acid (Mesalazine / Mesalamine)	Tablet 400mg	9.31	7.92	1 Tablet

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

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14/5/2024
(Dr. Vinod Kotwal)
Member Secretary