मिसिलस.- 8(127)/2024/डी.पी/एनपीपीए-डीवी-II
F. No. 8(127)/2024/DP/NPPA-Div. II

कार्यवाहीस. : 258/127/2024/F
Proceeding No: 258/127/2024/F

Draft Minutes of the 259th (overall) and 127th meeting of the Authority under DPCO, 2013 held on 08.10.2024 at 05.00 p.m.

The 259th meeting of the Authority (overall), which is the 127th meeting under the DPCO, 2013 was held on 08th October, 2024 at 05:00 p.m. under the Chairmanship of Dr. Arunish Chawla, 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 Minutes of the 126th Meeting held on 09.09.2024.

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 126thMeeting held on 09.09.2024.

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

4.1The Authority deliberated on 20 (Twenty) cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (xx) falling under the purview of Para 2(1)(u) of DPCO, 2013. The Authority approved the retail prices of 20 (Twenty) 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 Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.	4 (i)	Bisoprolol and Amlodipine Tablet	**Each Film Coated Tablet Contains:** Bisoprolol Fumarate IP 2.5 mg + Amlodipine Besilate IP eq. to Amlodipine 5 mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd./ M/s Abbott Healthcare Pvt. Ltd.	6.23
2.	4 (ii)	Bisoprolol and Amlodipine Tablet	**Each Film Coated Tablet Contains:** Bisoprolol fumarate IP 5 mg + Amlodipine Besilate IP eq. to Amlodipine 5 mg	1 Tablet	M/s Swiss Garnier Genexiaa Sciences Pvt. Ltd./ M/s Abbott Healthcare Pvt. Ltd.	8.34
3.	4 (iii)	Gentamicin and Dexamethasone Eye Drops	**Composition:** Gentamicin 0.3%w/v (as gentamicin sulphate IP 3000units/ml) + Dexamethasone IP 0.1%w/v (as Dexamethasone Sodium phosphate IP) Benzalkonium Chloride IP 0.01%w/v	1 ml	M/s HAB Pharmaceuticals & Research Ltd/ M/s Mankind Prime Labs Pvt Ltd.	2.01
4.	4 (iv)	Levosalbutamol and Ipratropium Bromide Respules	**Each 2.5 ml Respule contains:** Levosalbutamol Sulphate IP eq. to Levosalbutamol 1.25 mg + Ipratropium Bromide IP eq. to Ipratropium (Anhydrous) 500 mcg	1 ml	M/s Higgs Healthcare/ M/s Mankind Prime Labs Pvt Ltd.	5.75

S. No	Agend a no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
5.	4 (v)	Abacavir, Dolutegravir and Lamivudine Tablet	**Each film coated tablet Contains:** Abacavir Sulfate USP eq. to Abacavir 600 mg Dolutegravir Sodium eq. to Dolutegravir 50 mg Lamivudine USP 300 mg	1 Tablet	M/s. APL Healthcare Ltd./ M/s Aurobindo Pharma Ltd.	161.10
6.	4 (vi)	Atorvastatin, Aspirin and Clopidogrel Capsule	**Each hard gelatin Capsule Contains:** Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg + Atorvastatin Calcium IP eq. to Atorvastatin 20 mg (as film coated tablet) + Aspirin IP 75 mg (as enteric coated tablet)	1 Capsule	M/s Surien Pharmaceuticals (P) Ltd./ M/s Unison Pharmaceuticals Pvt. Ltd.	5.27
7.	4 (vii)	Atorvastatin, Aspirin and Clopidogrel Capsule	**Each hard gelatin Capsule Contains:** Clopidogrel Bisulphate IP eq. to Clopidogrel 75 mg + Atorvastatin Calcium IP eq. to Atorvastatin 10 mg (as film coated tablet) + Aspirin IP 75 mg (as enteric coated tablet)	1 Capsule	M/s Surien Pharmaceuticals (P) Ltd./ M/s Unison Pharmaceuticals Pvt. Ltd.	3.80
8.	4 (viii)	Cefuroxime Axetil Tablet	**Each Film Coated Tablet Contains:** Cefuroxime Axetil IP eq to Cefuroxime 250mg	1 Tablet	M/s Innova Captab Ltd/ M/s Dr Reddy's Laboratories Ltd	26.98
9.	4 (ix)	L-carnitine Mecobalamin and Folic Acid Tablet	**Each film coated Tablet Contains:** L-Carnitine L-Tartrate eq. to L-carnitine 500 mg Mecobalamin IP 1500 mcg Folic Acid IP 1.5 mg	1 Tablet	M/s J.K. Printpack (Pharma Division)/ M/s Cadila Pharmaceuticals Ltd.	14.50
10.	4(x)	Sitagliptin, Metformin Hydrochloride and Glimepiride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to	1 Tablet	M/s Synokem Pharmaceuticals Ltd/ M/s Unison	12.19

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
			Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2mg		Pharmaceuticals Pvt Ltd	
11.	4(xi)	Sitagliptin, Metformin Hydrochloride and Glimepiride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 1mg	1 Tablet	M/s Synokem Pharmaceuticals Ltd/ M/s Unison Pharmaceuticals Pvt Ltd	11.05
12.	4(xii)	Sitagliptin, Metformin Hydrochloride and Glimepiride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg Metformin Hydrochloride IP 1000mg Glimepiride IP 2mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Medley Pharmaceuticals Ltd	12.19
13.	4(xiii)	Sitagliptin, Metformin Hydrochloride and Glimepiride Tablet	**Each film coated tablet contains:** Sitagliptin Phosphate Monohydrate IP eq. to Sitagliptin 50mg + Metformin Hydrochloride IP 1000mg + Glimepiride IP 1mg	1 Tablet	M/s Exemed Pharmaceuticals/ M/s Medley Pharmaceuticals Ltd	11.05
14.	4(xiv)	Dapagliflozin, Sitagliptin and Metformin (ER) Tablet	**Each film coated bilayered tablet contains:** Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 500 mg (as Extended Release)	1 Tablet	M/s Synokem Pharmaceuticals Ltd/ M/s Primus Remedies Pvt Ltd	16.96
15.	4(xv)	Dapagliflozin, Sitagliptin and Metformin (ER) Tablet	**Each film coated bilayered tablet contains:** Dapagliflozin Propanediol	1 Tablet	M/s Synokem Pharmaceuticals Ltd/ M/s Primus Remedies Pvt Ltd	17.89

S. No	Agenda no.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Prices
(1)	(2)	(3)	(4)	(5)	(6)	(7)
			Monohydrate eq. to Dapagliflozin 10mg + Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100 mg + Metformin Hydrochloride IP 1000 mg (as Extended Release)			
16.	4(xvi)	Bisoprolol and Telmisartan Tablet	**Each Film Coated Bilayered Tablet Contains:** Bisoprolol Fumarate IP 2.5 mg + Telmisartan IP 40 mg	1 Tablet	M/s Mascot Health Series Pvt Ltd/ M/s Macleods Pharmaceuticals Ltd	9.65
17.	4(xvii)	Bisoprolol and Telmisartan Tablet	**Each Film Coated Bilayered Tablet Contains:** Bisoprolol Fumarate IP 5 mg + Telmisartan IP 40 mg	1 Tablet	M/s Mascot Health Series Pvt Ltd/ M/s Macleods Pharmaceuticals Ltd	11.21
18.	4(xviii)	Esomeprazole and Domperidone SR apsules	**Each hard gelatin capsule contains:** Esomeprazole Magnesium IP eq. to Esomeprazole 40 mg (as enteric coated pellets) Domperidone Maleate IP eq. to Domperidone 30 mg (Sustained release)	1 Capsule	M/s Windlas Biotech Ltd./ M/s Biological E. Ltd.	5.36
19,	4(xix)	Ceftriaxone and Tazobactam	**Each vial Contains:** Sterile Ceftriaxone Sodium IP eq to Ceftriaxone 250 mg Sterile Tazobactam Sodium IP eq to Tazobactam 31.25mg	1 vial	M/s GMH Organics/ M/s Aurobindo Pharma Ltd	66.92
20.	4(xx)	Ceftriaxone and Tazobactam	**Each vial Contains:** Sterile Ceftriaxone Sodium IP eq to Ceftriaxone 500 mg Sterile Tazobactam Sodium IP eq to Tazobactam 62.5mg	1 vial	M/s GMH Organics/ M/s Aurobindo Pharma Ltd	111.16

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

5.1 Noted.

6. Agenda item no. 6: Price fixation as per Pharmaceuticals Purchase Policy (PPP) for products of Pharma Central Public Sector Enterprises (CPSEs) and their subsidiaries.

6.1 Record note of discussion for members being circulated separately.

7. Additional Agenda item no. 1: Applications received in order to review and consider increase in the prices of various formulations under Para 19 of DPCO, 2013

7.1 Record note of discussion for members being circulated separately.

7.2 The Authority noted that NPPA has been receiving requests for upward price revision of various drugs under para 19 of DPCO, 2013 from the manufactures citing various reason like increase in cost of Active Pharmaceutical Ingredients (APIs); increase in the cost of production; change in exchange rate etc.; resulting in unviability in sustainable production and marketing of the drugs. Companies have also applied for discontinuation of some of the formulations on account of their unviability.

7.3 The Authority recalled that in 2019 NPPA referred the issue to the Committee on Affordable Medicines and Health Products (CAMHP, earlier known as SCAMHP), NITI Aayog, Government of India for guidance on the modalities/ methodology to be followed. CAMHP recommended an increase of 50% in the ceiling prices and also authorized NPPA to examine additional formulations / molecules experiencing similar issues of manufacturing unviability due to low prices and apply upward price revision on principles determined by CAMHP.

7.4 Accordingly, prices were increased for 21 formulations for 12 drugs in the 71st Authority meeting held on 09.12.2019 and for 9 formulations of 3 drugs in the 89th Authority meeting held on 28.06.2021

7.5 The Authority noted that NPPA has received applications for 76 formulations of 28 APIs. These have been examined by the Committee on Para 19 (Inter-Ministerial Committee) constituted by the Authority in its 65th meeting held on 27.03.2019 in its 6th & 7th meeting held on 14.03.2024 & 04.04.2024 respectively. The committee deliberated on the various applications based on the inputs/details/data available in the NPPA as well as data relating to API prices for the years 2020 to 2023 provided by the O/o DCGI. The Inter-Ministerial Committee in the meetings considered the applications on different parameters including 'essentiality' of these formulations;

market share of the companies requesting for price revision; the period since when the formulation is under price control; concern regarding possible shortages; request, if any for discontinuation received from the companies; and trend of API prices during the last three years from 2020 to 2023 as reported by the O/o DCGI.

7.6 The Authority noted that the Inter-Ministerial Committee in its report dated 05.04.2024 recommended the price revision for 14 formulations, rejected 46 formulations and deferred 16 formulations for further examination. It was also noted that subsequent to the submission of report on 05.04.2024 by the Inter-Ministerial Committee, another manufacturer with major market share has also applied for upward price revision of Lithium tablet 300mg which was recommended to be deferred by the Inter-Ministerial Committee. Further, request for upward price revision has also been received for Cefazolin injection 1 gm.

7.7 It was further noted that in respect of 4 formulations viz., Metronidazole tablet 200mg, 400mg, oral liquid 200 mg/5ml and injection 500 mg/100 ml, one of the applicant companies has requested that it would provide supporting data /research on the market dynamics and requested to hold/defer the application till further inputs are provided by the company. Therefore, the Authority directed that the matter may be placed before the Inter-Ministerial Committee upon receipt of further data from the company.

7.8 The Authority deliberated on the new applications received for upward price revision of Lithium 300 mg tablet and Cefazolin injection 1 gm subsequent to the submission of the report by the Inter-Ministerial Committee on 05.04.2024. It was noted by the Authority that application for Cefazolin injection 1 gm is a new application and has not been considered by the Inter-Ministerial Committee at all while the case of Lithium 300 mg tablet was considered by the committee but deferred for further examination as noted above in 7.6. An analysis of these two new applications was presented before the Authority and it was noted by the Authority that request for upward price revision for Cefazolin injection 1 gm of the same applicant was earlier too rejected by the Authority in its 75th meeting held on 20.05.2020 due to its negligible market share. As there was no change in the market share of the company, the request for price revision of Cefazolin injection 1 gm was not considered by the Authority. However, in the case of Lithium 300 mg tablet it was noted by the Authority based on the analysis presented before it that the two applicants put together have around 95% of the market share and the formulation has been under repeated price control (NLEM,2011 onwards). Hence, the Authority decided to consider Lithium 300 mg tablet for upward price revision.

7.9 The Authority noted that the formulations recommended by the Inter-Ministerial Committee for upward price revision are mostly low-priced scheduled formulations and have been under repeated price control, but are generally used as first line of

treatment and are important to address the public health needs of the country. Further, the mandate of NPPA is to ensure availability of drugs at affordable prices. While ensuring affordability, access cannot be jeopardized and the life-saving essential drugs must remain available to the general public at all times.

7.10 Therefore, unviability of these formulations should not lead to a situation, where these drugs become unavailable in the market and the public is forced to switch to expensive alternatives. Hence, the Authority agreed to the recommendation of the committee. Therefore, in view of the above, the Authority invoked extraordinary powers in public interest under para 19 of DPCO, 2013 for upward price revision of the ceiling process of following eleven (11) formulations of 8 drugs by giving one time increase of 50%, as per the guidance of CAMHP, from the present applicable ceiling prices as mentioned in the table below:

Table No. 2: Revision in ceiling prices of Eleven scheduled formulations

S. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Approved revised Ceiling Price (Rs.) excluding GST	Existing S.O. No. & Date	
(1)	(2)	(3)	(4)	(5)	6(a)	6(b)
1.	Benzyl Penicillin	Powder for Injection 10 Lac Units	Each Pack	14.57	1548(E) Sl. No. 24	26.03.2024
2.	Atropine	Injection 0.6mg/ml	1 ML	6.86	1547(E) Sl. No. 64	26.03.2024
3.	Streptomycin	Powder for Injection 750 mg	1 Vial	15.15	1547(E) Sl. No. 617	26.03.2024
4.	Streptomycin	Powder for Injection 1000 mg	1 Vial	16.29	1547(E) Sl. No. 618	26.03.2024
5.	Salbutamol	Tablet 2 mg	1 Tablet	0.27	1547(E) Sl. No. 596	26.03.2024
6.	Salbutamol	Tablet 4 mg	1 Tablet	0.32	1547(E) Sl. No. 595	26.03.2024
7.	Salbutamol	Respirator Solution (Solution for Nebulizer 5mg/mL)	1 ml	1.02	1547(E) Sl. No. 599	26.03.2024
8.	Pilocarpine	Drops 2%	1 ml	16.25	1547(E)	26.03.2024

					Sl. No. 535	
9.	Cefadroxil	Tablet 500 mg	1 Tablet	6.71	1547(E) Sl. No. 114	26.03.2024
10.	Desferrioxamine	Powder for injection 500mg	1 Vial	282.98	1547(E) Sl. No. 705	26.03.2024
11.	Lithium	Tablet 300mg	1 Tablet	2.45	1547(E) Sl. No. 411	26.03.2024

7.11 Further, the provision of Para 13(2) of DPCO,2013 would not be applicable on the revised ceiling prices of the formulations mentioned in para 7.10 above and these formulations being scheduled formulation would be allowed the annual price increase as per Wholesale Price Index (WPI).

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

वि. कोटवाल 14/10/2024

(Dr. Vinod Kotwal)
Member Secretary