मिसिलस.- 8(113)/2023/डी.पी/एनपीपीए-डीवी-II
F. No. 8(113)/2023/DP/NPPA-Div. II

कार्यवाहीस. : 245/113/2023/F
Proceeding No: 245/113/2023/F

Minutes of the 245th(overall) and 113thmeeting of the Authority under DPCO, 2013 held on 26.05.2023 at 03:00 PM.

The 245th meeting of the Authority (overall), which is the 113thmeeting under the DPCO, 2013, was held on 26thMay, 2023 at 03:00 P.M. 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 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) Shri G.L. Gupta, Director (M&E)
(iv) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
(v) Shri Saurabh Bansal, Deputy Director (M&E)
(vi) Shri Mahaveer Saini, Deputy Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 112thMeeting held on 01.05.2023.

1.1 The Authority confirmed the minuteswithout any change.

2. Agenda item no. 2 – (a) Action Taken Report (ATR) on decisions taken by NPPA in its 112thMeeting held on 01.05.2023.

2.1 Noted.

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

3.1 Noted. The Authority further noted that M/S Dr. Reddy's Laboratories has been allowed to withdraw their application for 'each hard gelatin capsule containing: Esomeprazole Magnesium Trihydrate IP eq. to Esomeprazole 40mg (as Enteric coated pellets) + Domperidone IP (as Sustained release pellets) 30mg', working

sheet of which was uploaded on NPPA website on 24.04.2023. The withdrawal was permitted as neither M/S Dr. Reddy's Laboratories (Applicant marketing company) nor M/s Inventia Healthcare Limited (Manufacturer) were the existing manufacturer of the said proposed new drug as per provisions of DPCO, 2013.

4. Agenda item no. 4 – New Drug applications for Price fixation under Para 5 and Para 15 of DPCO, 2013

4.1 The Authority discussed the following cases of retail pricefixation of new drugs as presented in Agenda no. 4 (i) to 4 (xxiii)(total 23 Form I applications containing retail price fixation of 23 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 23(twenty-three) new drugs under Para 5 and 15 of the DPCO 2013, as detailed in **Table 1:**

Table No. 1: Retail price fixation of new drugs

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (i)	Trypsin, Bromelain, Rutoside Trihydrate and Diclofenac Sodium Tablets	**Each enteric coated tablet contains:** Trypsin BP 48mg Bromelain 90mg Rutoside Trihydrate BP 100mg Diclofenac Sodium IP 50mg	1 Tablet	M/s Synokem Pharmaceuticals Limited / M/s Troikaa Pharmaceuticals Ltd.	20.51
4 (ii)	Gliclazide ER and Metformin Hydrochloride (ER) Tablets	**Each uncoated bilayered tablet contains:** Gliclazide IP 60mg (as extended release form) Metformin Hydrochloride IP 1000mg (as extended release form)	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Mankind Pharma Ltd.	10.03
4 (iii)	Telmisartan, Chlorthalidone & Cilnidipine tablets	**Each film coated tablet contains:** Telmisartan IP 40mg Chlorthalidone IP 6.25mg Cilnidipine IP 10mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Eris Lifesciences Limited	13.17
4 (iv)	Amoxycillin and Potassium Clavulanate Oral Suspension IP	**Each 5ml of constituted suspension contains:** Amoxycillin Trihydrate IP eq. to Amoxycillin 400mg Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 57mg	1 ml	M/s Alps Communication Pvt. Ltd. / M/s Mankind Prime Labs Pvt. Ltd.	4.05

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (v)	Aceclofenac + Paracetamol + Serratiopeptidase Tablet	**Each film coated tablet contains:** Aceclofenac IP 100mg, Paracetamol IP 325mg Serratiopeptidase IP 10mg (As enteric coated granules eq. to 20000 enzyme activity unit of serratiopeptidase)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. /M/s German Remedies Pharmaceuticals Pvt. Ltd.	5.23
4 (vi)	Aceclofenac + Paracetamol + Serratiopeptidase Tablet	**Each film coated tablet contains:** Aceclofenac IP 100mg, Paracetamol IP 325mg Serratiopeptidase IP 15mg (As enteric coated granules eq. to 30000 enzyme activity unit of serratiopeptidase)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. /M/s German Remedies Pharmaceuticals Pvt. Ltd.	8.09
4 (vii)	Ofloxacin and Metronidazole suspension	**Each 5ml contains:** Ofloxacin IP 50mg Metronidazole Benzoate IP eq. to Metronidazole 100mg	1 ml	M/s Skymap Pharmaceuticals Pvt. Ltd./ M/s German Remedies Pharmaceuticals Pvt. Ltd.	0.72
4 (viii)	Diclofenac Diethylamine, Methyl Salicylate, Menthol & Virgin Linseed Oil Topical Spray	**Composition:** Diclofenac Diethylamine IP 1.16%w/w eq. to Diclofenac Sodium IP 1% Virgin Linseed Oil BP 3% w/w Methyl Salicylate IP 10% w/w Menthol IP 5%w/w	1 Gm	M/s Pontika Aerotech Limited / M/s Abbott Healthcare Pvt. Ltd.	2.69
4 (ix)	Alpha Lipoic Acid, Methylcobalamin, Vitamin B6, Folic Acid, Benfotaimine, Biotin & Chromium Picolinate Capsule	**Each hard gelatin capsule contains:** Alpha Lipoic Acid USP 100mg Methylcobalamin IP 1500mcg Vitamin B6 IP 3mg Folic Acid IP 1.5mg Benfotaimine 50mg Biotin USP 5mg Chromium Picolinate USP eq. to Chromium 200mcg	1 Capsule	M/s Theon Pharmaceuticals Ltd. / M/s German Remedies Pharmaceuticals Pvt. Ltd.	13.57
4 (x)	Lidocaine &	**Each actuation spray contains:**Lidocaine	1 Gm	M/s Pontika	34.52

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Prilocaine Spray	7.5mg, Prilocaine 2.5mg		Aerotech Limited / M/s Mankind Pharma Ltd.	
4 (xi)	Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate Oral Suspension	**Each 5ml contains:** Sodium Alginate IP 250mg Sodium Bicarbonate IP 133.5mg Calcium Carbonate IP 80mg	1 ml	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Mankind Pharma Ltd.	0.88
4 (xii)	Atorvastatin, Clopidogrel & Aspirin Capsule	**Each hard gelatin capsule contains:** Atorvastatin Calcium IP eq. to Atorvastatin 40mg (As white coloured pellets) Clopidogrel Bisulphate IP eq. to Clopidogrel 75mg (As two reddish brown coloured film coated tablets, 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 Zydus Healthcare Limited	13.22
4 (xiii)	Telmisartan and Bisoprolol Fumarate Tablets	**Each film coated tablet contains:** Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Emcure Pharmaceuticals Limited	10.97
4 (xiv)	Telmisartan and Bisoprolol Fumarate Tablets	**Each film coated tablet contains:** Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Emcure Pharmaceuticals Limited	12.62
4 (xv)	Telmisartan and Bisoprolol Fumarate Tablets	**Each film coated table contains:** Telmisartan IP 40mg Bisoprolol Fumarate IP 2.5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Alembic Pharmaceuticals Ltd.	9.82
4 (xvi)	Telmisartan and Bisoprolol Fumarate Tablets	**Each film coated table contains:** Telmisartan IP 40mg Bisoprolol Fumarate IP 5mg	1 Tablet	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Alembic Pharmaceuticals Ltd.	11.60
4 (xvii)	Azelnidipine and	**Each uncoated**	1 Tablet	M/s Mascot	17.96

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Telmisartan Tablet	**bilayered tablet contains:** Azelnidipine IP 16mg Telmisartan IP 40mg.		Health Series Pvt. Ltd. / M/s Torrent Pharmaceuticals Limited	
4 (xviii)	Azelnidipine and Telmisartan Tablet	Each uncoated bilayered tablet contains: Azelnidipine IP 16mg Telmisartan IP 40mg.	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Glenmark Pharmaceuticals Limited	17.82
4 (xix)	Paracetamol and Caffeine Tablets IP	**Each uncoated tablet contains:** Paracetamol IP 500mg Caffeine IP 50mg	1 Tablet	M/s Troikaa Pharmaceuticals Limited	1.77
4 (xx)	Atorvastatin and Bempedoic Acid Tablets	**Each film coated tablet contains:** Bempedoic Acid 180mg Atorvastatin Calcium IP eq. to Atorvastatin 80mg	1 Tablet	M/s Exemed Pharmaceuticals / M/s Eris Lifesciences Limited	52.97
4 (xxi)	Ofloxacin & Dexamethasone Sodium Phosphate Eye/Ear Drops	**Composition:** Ofloxacin IP 0.3%w/v Dexamethasone Sodium Phosphate IP 0.1% w/v Benzalkonium Chloride Sodium IP 0.02% v/v (As preservative) Sterile aqueous Vehicle q.s.	1 ml	M/s Skymap Healthcare Pvt. Ltd. /M/s Healing Pharma India Pvt. Ltd.	5.80
4 (xxii)	Bilastine and Montelukast Oral Suspension	**Each 5ml suspension contains:** Bilastine 10mg Montelukast Sodium IP eq. to Montelukast 4mg	1 ml	M/s Ravenbhel Healthcare Pvt. Ltd. / M/s Aristo Pharmaceuticals Pvt. Ltd.	1.71
4 (xxiii)	Formoterol Fumarate and Budesonide Respirator Suspension	**Each 2ml pulmule contains:** Formoterol Fumarate Dihydrate IP eq. to Foroterol Fumarate 20mcg Budesonide IP 1mg	Per Pulmule of 2 ml	M/s Alkem Laboratories Limited	56.20

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

5.1 Noted.

6. Agenda item no. 6 –Minutes of 50th meeting of Multidisciplinary Committee of Experts held on 21.04.2023.

6.1 Noted

7. Agenda item no. 7 –Application by M/s TroikaaPharmaceuticals Limited for exemption from the provisions of Drug Price Control Order 2013 under Para 32 (i) to (iii) for the formulations "Paracetamol Injection (Intramuscular) 250mg/ml" – reg.

7.1The matter relates to exemption under Para 32 (i) to (iii) for the formulation "Paracetamol Injection (Intramuscular) 250mg/ml" applied by M/s Troikaa Pharmaceuticals Limited vide e-mail dated 01.10.2022. The applicant vide letter dated 10.11.2022 submitted the copy of Patent issued by the Patent Office under Indian Patent Act, 1970 dated 09.11.2022 for "Novel Composition comprising Paracetamol and process for preparing the same" bearing registration no. 411067 along with the claim filed with Patent Office (Application No. 630/MUM/2010) dated 09.10.2010.

7.2 The Authority noted that the matter was deliberated in 47th and 50th Meeting of Multidisciplinary Committee of Experts (MDC) held on 02.12.2022 and 21.04.2023 respectively. The Authority deliberated on the matter and observed that further clarity is required on the application and the innovation claimed by M/s Troikaa Pharmaceuticals Limited for Paracetamol Injection (Intramuscular) 250mg/ml. Hence, information on following would also be required:

(a) The company may clearly clarify the exemption sought under which specific section of DPCO, 2013 i.e. 32(i)/32(ii)/32(iii) with reasons.
(b) Detailed inputs of the Office of DCGI regarding the approval of the said drug.

7.3 On receipt of these inputs, the case may be taken to MDC again for examining the case holistically keeping in view the innovation claimed for the said drug.

8. Agenda item no. 8 - Guidelines for application received from the marketers for change in manufacturer for the formulations for which retail price already notified and product launched in the market.

8.1 The Authority noted that the issue relating to change of manufacturer by the marketing companies was deliberated in earlier two authority meetings i.e. 99th and 111th meeting held on 28.06.2022 and 29.03.2023 respectively.

8.2 The Authority noted that requests made in earlier applications were permitted by NPPA keeping in view the unavoidable circumstances highlighted by the marketing companies in their submission to NPPA. One company had informed that in order to support environmentally sustainable business through reduction in supplier footprint, in line with their commitment as per Environmental Social and Governance (ESG) Policy, they were changing the manufacturer. The change was allowed keeping in view the circumstances mentioned by the applicant marketing companies and provisions of Para 15(2) of DPCO, 2013. After detailed discussion, the Authority had allowed the companies to continue marketing the formulation while keeping the same brand name with the changed manufacturer at the price not exceeding the present applicable retail price. This was also keeping in view the overall vision of the government for promoting Ease of Doing Business.

8.3The Authority, however, observed that subsequent to the above, companies have started applying to NPPA on a routine basis for change of manufacturer and are now merely intimating about the change citing reasons including change in business strategy, planning to manufacture the formulation at their own plant, etc.

8.4. The Authority noted that the change of manufacturer was allowed to the companies keeping in view the provisions of the DPCO 2013, the guidelines and specific circumstances of the company concerned. However, it is observed that companies are making it a routine affair and have started making unauthorized use of the same without seeking permission from NPPA. The Authority deliberated in detail on the implications of the same in view of applications and representation received.

8.5 After detailed deliberations, the Authority decided that all future cases of change of manufacturer shall be examined on following parameters on a case to case basis. Cases falling within the ambit of these parameters may be permitted change in manufacturer:

i. Cancellation/ seizure of license of the manufacturing company
ii. Natural calamity/civil riots leading to destruction of plant of manufacturing company
iii. Dissolution/ winding up of the manufacturing company
iv. Closure of the concerned business segment by the manufacturing company, etc.
v. Any other circumstance(s) proved to be beyond the control of manufacturer/ marketer

The onus to prove the above conditions requesting for change of manufacturer will be on the applicant company with documentary evidence. The requests will be examined on case to case basis and the earlier cases may not be treated as a precedent for future cases.

9. Agenda item no. 9 – Application for "Special Feature rate" for scheduled products (i) Tazofic Injection 2.25 gm containing Piperacillin 2gm + Tazobactum 250mg and (ii)Tazofic Injection4.5gm containing Piperacillin 4gm Tazobactam 500 mg under Para 11(3) of DPCO 2013.

9.1 The Authority noted that the matter was discussed in various meetings of MDC. As per the deliberations held in 45th meeting of the MDC held on 13.09.2022, additional 15 percent price over the present applicable ceiling price of the formulation for incremental innovation of the packaging was recommended.

9.2 The Authority noted that M/s Gufic Biosciences Ltd made representation on the recommendation made by the MDC vide' letter dated 23.09.2022. The matter was deliberated in the 102nd meeting of Authority held on 27.09.2022 and the matter was referred back to the MDC for examination of representation of the applicant.

9.3 The MDC in its 46th meeting held on 20.10.2022 noted the representation of the company and after deliberation decided that the company may be asked to submit

additional literature to substantiate their claim and also to make a presentation in the next meeting of the committee.

9.4 The Authority noted that a letter dated 27.10.2022 was sent to M/s Gufic Biosciences Ltd requesting to submit the additional literature to substantiate their claim and also to make presentation in the next meeting of the committee. Further, the matter was deliberated in 47th meeting of MDC held on 02.12.2022, wherein it was decided that the matter of separate price approval on account special packaging may be taken up after notification of ceiling price of the formulation under Revised Schedule-I of DPCO, 2013 (NLEM 2022).

9.5 Accordingly, the matter was deliberated by the MDC in its 50th meeting held on 26.04.2023 where in the committee noted that the ceiling price for the FDC of 'Piperacillin +Tazobactam' has been notified by NPPA vide S.O. No. 87(E) dated 06.01.2023 under NLEM, 2022. Further, the committee also noted that applicant i.e. M/s Gufic Biosciences Ltd has not submitted the additional literature to substantiate their claim as per NPPA's letter dated 27.10.2022. Therefore, after deliberations the committee recommended to reject the application of separate ceiling price of M/s Gufic Biosciences Ltd.

9.6 The Authority deliberated on the above matter including the MDC recommendations and decided to refer the matter back to the committee seeking clarification on the recommendation as to :

(a) Whether the request of applicant for price increase over & above 15% has been rejected, thereby recommending 15% additional price over current ceiling price; or

(b) The complete application for separate ceiling price has been recommended for rejection.

10. Agenda item no. 10 - Fixation of Ceiling Pricesof 20 Scheduled formulations under Revised Schedule-I (NLEM, 2022).

10.1 The Authority noted that prices of 671 formulations have been notified 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.

10.2 The Authority noted that ceiling prices for 20 scheduled formulations were uploaded on the NPPA website on 11.05.2023 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.

10.3The Authority was apprised that a total of 7 representations for 8 formulations have been received from companies. 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

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. The same have been dealt as decided in the 111th Authority meeting.

iii. Representation that monopoly reduction as per 6(1) not applicable since the formulation was covered under DPCO, 1995 and Para 6(2) exempts from monopoly reduction. The same has been considered and agreed as per provisions of DPCO, 2013.

10.4The Authority deliberated upon the ceiling price fixation of scheduled formulations and approved the following 16 formulations under Para 6(1) and 6(2) of DPCO 2013:

Table 1: Ceiling Price fixation under Para 6(1)& 6(2) 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	1.1.8	Thiopentone	Powder for injection 1g	61.52	(S.O. 1573(E) dated 31.03.2023)	55.32	1 Vial
2	1.1.8	Thiopentone	Powder for injection 0.5g	50.71	(S.O. 1573(E) dated 31.03.2023)	45.69	1 Vial
3	11.2.1	Framycetin	Cream1 %	New Added	New Added	1.66	1 GM
4	11.5.1	Permethrin	Gel 5%	1.82	(S.O. 1573(E) dated 31.03.2023)	1.31	1 GM

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)
5	5.2.4	Sumatriptan	Tablet 25mg	41.44	(S.O. 1573(E) dated 31.03.2023)	32.5	1 Tablet
6	5.2.4	Sumatriptan	Tablet 50mg	64.15	(S.O. 1573(E) dated 31.03.2023)	55.68	1 Tablet
7	6.3.1	Clofazimine	Capsule100mg	4.61	(S.O. 1573(E) dated 31.03.2023)	3.98	1 Capsule
8	6.3.1	Clofazimine	Capsule 50mg	2.70	(S.O. 1573(E) dated 31.03.2023)	2.11	1 Capsule
9	6.3.2	Dapsone	Tablet 100 mg	0.44	(S.O. 1573(E) dated 31.03.2023)	0.41	1 Tablet
10	6.4.9	Isoniazid	Tablet 300mg	1.49	(S.O. 1573(E) dated 31.03.2023)	1.29	1 Tablet
11	6.4.9	Isoniazid	Tablet 100mg	0.84	(S.O. 1573(E) dated 31.03.2023)	0.65	1 Tablet
12	18.1.2	Fludrocortisone	Tablet0.1mg	New Added	New Added	13.2	1 Tablet
13	8.2.6	Warfarin	Tablet5 mg	2.92	(S.O. 1573(E) dated 31.03.2023)	2.4	1 Tablet
14	8.2.6	Warfarin	Tablet3 mg	3.89	(S.O. 1573(E) dated 31.03.2023)	3.18	1 Tablet
15	8.2.6	Warfarin	Tablet2 mg	3.31	(S.O. 1573(E) dated 31.03.2023)	2.72	1 Tablet
16	8.2.6	Warfarin	Tablet1 mg	3.00	(S.O. 1573(E) dated 31.03.2023)	2.46	1 Tablet
17	1.4.4	Succinylcholine**(Note 1)**	Injection 50mg/mL	6.02	(S.O. 1573(E) dated 31.03.2023)	5.21	1 ML

Note 1: The Authority noted that representation received from the companies contending that their annual sales is different than as reported in worksheet based on Pharmatrac and correct PTR i.e. after availing WPI increase is not appearing in database. The Authority deliberated on the matter and reiterated the methodology approved in 104th meeting held on 23.11.2022 and practice adopted for ceiling price fixation under NLEM, 2022. Accordingly, Authority decided to use the Pharmatrac database only and agreed to only correction in PTR as Form-II/Form-V submitted by the companies in prescribed time as per provisions of DPCO, 2013.

10.5The Authority deliberated upon the ceiling price fixation of scheduled formulations and approved the following formulation under Para 19 of DPCO 2013:

Table 2: Ceiling Price fixation under Para 19 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	21.4.2	Latanoprost	Drops 0.005%	New added		232.57	1 ML

10.6 The Authority deliberated upon the ceiling price fixation of scheduled formulations and directed that the representations in respect of two formulations i.e. Dabigatran Capsule 110 mg and Dabigatran 150 mg may be re examined.

11. Agenda item no. 11 - Form-IV Intimation by M/s GlaxoSmithKline Pharmaceutical Limited (GSK) for discontinuation of the scheduled formulation viz., Grisovin FP 250mg Tablet containing Griseofulvin250 mg under para 21(2) of DPCO, 2013.

11.1 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 up to 31.05.2024 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.

It was noted by the Authority members that Shri Sachdeva, Advisor (Cost-I) is likely to be relieved from NPPA on his promotion. The Authority members and the officers present in the meeting placed on record their appreciation of the excellent work done by Shri Sachdeva in his tenure at NPPA particularly the extensive work undertaken during revision of ceiling prices as per NLEM, 2022.

After this, the meeting ended with a vote of thanks to the Chair and all the participants in the meeting.

वि. कोटवाल
8/6/2023

(Dr. Vinod Kotwal)
Member Secretary