

मिसिलस.- 8(119)/2023/डी.पी/एनपीपीए-डीवी-II
F. No. 8(119)/2023/DP/NPPA-Div. II

कार्यवाहीस. : 251/119/2023/F
Proceeding No: 251/119/2023/F

Minutes of the 251st(overall) and 119thmeeting of the Authority' under DPCO, 2013 held on 15.12.2023 at 11:30 AM.

The 251st meeting of the Authority (overall), which is the 119th meeting under the DPCO, 2013 was held on 15th December, 2023 at 11:30 AM 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
- (iv) Dr. Rajeev Singh Raghuvanshi, Drugs Controller General of India, CDSCO, Ministry of Health & Family Welfare (through V.C.)

Shri A. K. Pradhan, Jt. 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-I)
- (ii) Ms. Rashmi Tahiliani, Jt. Director (Pricing)
- (iii) Shri. Saurabh , Deputy Director (M&E)
- (iv) Ms. Yuvika Panwar, Assistant Director (Pricing)

II. Agenda items

1. Agenda item no. 1 - Confirmation of Minutes of the 118thMeeting held on 09.11.2023.

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 118thMeeting held on 09.11.2023.

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 discussed the following cases of retail price fixation of new drugs as presented in Agenda no. 4 (i) to 4 (xix) (total 19 Form I applications containing retail price fixation of 19 new drug) falling under the purview of Para 2(1)(u) of DPCO, 2013 and approved the retail prices of 19 (nineteen) 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 (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (i)	Bisoprolol Fumarate & Amlodipine tablet	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5mg Amlodipine Besylate IP Eq. to Amlodipine 5mg	1 Tablet	M/s Swiss Garniers Biotech Private Limited / M/s Zydus Healthcare Limited	6.74
4 (ii)	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 unity of serratiopeptidase)	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Apex Laboratories Private Limited	8.00
4 (iii)	Povidone Iodine Gargle	Contains: Povidone-Iodine IP 2% w/v (Available Iodine 0.2w/v)	1 ML	M/s Stedman Pharmaceuticals Pvt. Ltd.	1.93
4 (iv)	Amoxicillin + Potassium Clavulanate Tablets IP	Each film coated tablet contains: Amoxicillin Trihydrate eq. to Amoxicillin IP 875mg Potassium Clavulanate Diluted eq. to Clavulanic Acid IP 125mg	1 Tablet	M/s Theon Pharmaceuticals Ltd. / M/s J.B. Chemicals & Pharmaceuticals Ltd.	40.03
4 (v)	Bilastine and	Each film coated	1	M/s Ravenbhel	13.02

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
	Montelukast Tablets	tablet contains: Montelukast Sodium IP Eq. to Montelukast 10mg Bilastine 20mg	Tablet	Healthcare Pvt. Ltd. / M/s Cadila Pharmaceuticals Ltd.	
4 (vi)	Telmisartan and Metoprolol Succinate (ER) Tablet	Each film coated bilayered tablet contains: Telmisartan IP 40mg Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate 50mg (as extended release form)	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s La Renon Healthcare Pvt. Ltd.	13.39
4 (vii)	Metoprolol Succinate Extended Release & Cilnidipine Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate IP 25mg (As Extended release) Cilnidipine IP 10mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Limited	9.12
4 (viii)	Metoprolol Succinate Extended Release & Cilnidipine Tablet	Each film coated bilayered tablet contains: Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate IP 50mg (As Extended release) Cilnidipine IP 10mg	1 Tablet	M/s Pure and Cure Healthcare Pvt. Ltd. / M/s Cipla Limited	10.21
4 (ix)	Trastuzumab 150mg	Combipack contains: Vial-1 Lyophilized Powder concentrate for solution for Intravenous Infusion, Multi use vial Composition: Trastuzumab (r-DNA Origin) IH (Active ingredient) 150mg, α,α -Trehalose	1 Vial	M/s Hetero Biopharma Limited / M/s Mankind Pharma Limited	15817.49

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
		Dihydrate USP (as Lyoprotectant) 136.2mg L-Histidine Hydrochloride Monohydrate EP (as buffering agent) 3.36mg L-Histidine USP (as buffering agent) 2.16mg Polysorbate 20 IP (as surfactant) 0.6mg Vial -2 Bacteriostatic Water for Injection 10 ml Single use vial Composition: Benzyl Alcohol IP 1.1% V/V Water for Injection			
4 (x)	Sucralfate, Metronidazole and Lignocaine Hydrochloride Cream	Composition: Sucralfate IP 7.0% w/w Metronidazole IP 1.0% w/w Lignocaine Hydrochloride IP 4.0% w/w Cream base q.s.	Per Gram	M/s Stedman Pharmaceutics Pvt. Ltd.	4.45 (Note1)
4 (xi)	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 La Renon Healthcare Pvt Ltd	9.73
4 (xii)	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 La Renon Healthcare Pvt Ltd	11.22
4 (xiii)	Bisoprolol Fumarate and Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 2.5 mg Telmisartan IP 40 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Zydus Healthcare Ltd.	9.73

Agenda No.	Name of the Formulation / Brand Name	Strength	Unit	Manufacturer & Marketing Company	Retail Price (in Rs.)
(1)	(2)	(3)	(4)	(5)	(6)
4 (xiv)	Bisoprolol Fumarate and Telmisartan Tablets	Each film coated tablet contains: Bisoprolol Fumarate IP 5 mg Telmisartan IP 40 mg	1 Tablet	M/s Mascot Health Series Pvt. Ltd. / M/s Zydus Healthcare Ltd.	11.22
4 (xv)	Norethisterone Acetate Controlled Release Tablet	Each Film Coated Controlled Release tablet contains: Norethisterone Acetate BP 10mg	1 Tablet	M/s Akums Drugs & Pharmaceuticals Ltd. / M/s Group Pharmaceuticals Ltd.	15.80
4 (xvi)	Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate Oral Suspension	Each 5 ml contains: Sodium Alginate IP 250mg Sodium Bicarbonate IP 133.5mg Calcium Carbonate IP 80mg In a Flavoured base q.s.	1 ml	M/s Skymap Pharmaceuticals Pvt. Ltd.	0.90
4 (xvii)	Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate Oral Suspension	Each 5 ml contains: Sodium Alginate IP 250mg Sodium Bicarbonate IP 133.5mg Calcium Carbonate IP 80mg In a Flavoured base q.s.	1 ml	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Glensmith Labs Pvt. Ltd.	0.90
4 (xviii)	Sodium Alginate, Sodium Bicarbonate & Calcium Carbonate Oral Suspension	Each 5 ml contains: Sodium Alginate IP 250mg Sodium Bicarbonate IP 133.5mg Calcium Carbonate IP 80mg In a Flavoured base q.s.	1 ml	M/s Skymap Pharmaceuticals Pvt. Ltd. / M/s Jagsonpal Pharmaceuticals Ltd.	0.90
4 (xix)	Albendazole & Ivermectin Tablets	Each uncoated chewable tablet contains: Albendazole IP 400mg Ivermectin IP 6mg	Tablet	M/s IBN Herbals / M/s Indoco Remedies Limited	24.63 (Note 2)

Note 1- Representation was received from the M/s Stedman Pharmaceuticals Pvt. Ltd. stating that the market price of the brands considered in the draft uploaded working sheet are much lower than their current market price. In this regard, the Authority noted that in the draft working sheet PTR i.e., price to the retailer is considered and retail price is calculated by adding 16% margin in average PTR.

Note 2-The Authority noted that applicant M/s Indoco Remedies Limited in their Form-I application claimed retail price of Rs.3.50 per tablet. However, when the draft working sheet was uploaded M/s Indoco Remedies Limited filed a representation stating that Retail price has been inadvertently mentioned as Rs 3.50 per tablet instead of Rs 35.00 per tablet and that this is a typographical error. The Authority deliberated on the matter and noted that PTR of other qualifying brands with more than 1% market share are in the range of Rs. 19.29 per tablet to Rs. 24.43 per tablet and the average PTR is Rs 21.23 per tablet. In view of this, Authority decided to consider the representation of the company and consider the claimed price as Rs.35.00 per tablet instead of Rs.3.5 per tablet. Accordingly, the Authority approved retail prices as Rs. 24.63 per tablet excluding taxes (i.e. lower of the worked out price and claimed price).

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

5.1 Noted

6. Agenda item no. 6 –Fixation of Ceiling Price of scheduled formulations under Revised Schedule-I (NLEM, 2022) based on October 2023 database.

6.1 The agenda for fixation of Ceiling Price of scheduled formulation under NLEM,2022 based on October, 2023 data as available in the market data base for the month of October, 2023 was placed before the Authority. The Authority noted that in 104th Authority meeting held on 23.11.2022, it was decided that data for July, 2022 and Pharmatrac database of July, 2022 shall be considered for fixation of ceiling prices under NLEM 2022.

6.2 The Authority also noted that till 15.12.2023 NPPA has fixed ceiling prices of 700 formulations under NLEM, 2022 using July, 2022 as available in the market data base for the month database of July, 2022. Further, ceiling prices of approximately 225 formulations are yet to be fixed.

6.3 The proposal regarding fixation of remaining ceiling price under NLEM, 2022 using database of October, 2023 was deliberated in the Authority and it was decided that matter may be examined further and placed in the next Authority meeting.

7. Agenda item no. 7 –Revision in retail prices fixed under Para 5 of DPCO, 2013- Retail price fixation under Para 5 of DPCO, 2013 –Each Vial contains: Ceftazidime Pentahydrate IP Eq. to Ceftazidime 2.0 gm + Avibactam Sodium eq. to Avibactam 0.5 gm.

7.1 Form I application from M/s Samarth life Sciences Private Limited (Marketer) and M/s Protech Telelinks (Manufacturer) for the subject formulation was placed in the



114th Authority Meeting based on Pharmatrac data. However, it was directed by the Authority to reexamine the issue as the price was being fixed based on one brand only under Para 5 of DPCO, 2013 read with Para 4(1). It was discussed that there might be a possibility of either the product being patented or there might be other players also in the market but not captured in the Pharmatrac database. Hence, the Authority decided to defer the agenda item with direction to further re-examine the matter.

7.2 The matter was examined and it was found that FDC of 'Avibactam+Ceftazidime' was a patented product, which has become off-patent in January, 2023. The patent holder was M/s Pfizer Ireland Pharmaceuticals. Accordingly, form I application from M/s Samarth life Sciences Private Limited (Marketer) and M/s Protech Telelinks (Manufacturer) for the subject formulation is under examination.

7.3 In this connection, the Authority also recalled that NPPA has notified retail prices of the subject formulation at Rs.2500.00 for M/s Cipla Limited (Manufacturer & Marketer) vide S.O. No. 5973 (E) dated 19.12.2022 as against the worked out price of Rs.3773.31/-. NPPA also notified retail price of Rs.3773.31 for M/s BDR Pharmaceuticals International Pvt. Ltd. (Manufacturer) & M/S Wockhardt Ltd. (Marketer) vide S.O. No. 1434 (E) dated 27.03.2022 as against claimed price of Rs.5267.85/-. These prices were calculated as per Para 5(1) read with Para 4(1) of DPCO, 2013 based on Pharmatrac data i.e. without applying 50% reduction as applicable in case of off-patented drug, since fact about the said formulation about to become off-patent/has become off-patent was not known at the time of retail price fixation for the said two applications.

7.4 The Authority noted that had the fact regarding subject formulation about to become off-patent / has become off-patent was known earlier, the prices would have been calculated by applying 50% reduction so as to pass on the benefit of the drug becoming off-patent to the consumers, in line with practice being followed by NPPA at that time. It was noted by the Authority that based on this principle, the worked out retail price of each vial containing Ceftazidime Pentahydrate IP Eq. to Ceftazidime 2.0 gm + Avibactam Sodium eq. to Avibactam 0.5 gm in respect of M/S Cipla Limited (Manufacturer & Marketer) and M/s BDR Pharmaceuticals International Pvt. Ltd. (Manufacturer) & M/S Wockhardt Ltd. (Marketer) would be Rs.1886.66 (i. e 50% of Rs.3773.31/-).

7.5 As the worked out price as detailed in para above is lower than the claimed price, the Authority henceforth, approved the retail price at Rs.1886.66/- for the said formulation for M/s Cipla Limited (Manufacturer & Marketer) and M/s BDR Pharmaceuticals International Pvt. Ltd. (Manufacturer) & M/S Wockhardt Ltd. (Marketer).

8. Agenda item no. 8 -Retail Price fixation of new drugs for which MDC has already recommended a methodology.

8.1 The Authority deliberated in detail the recommendation of the MDC that the retail price recommended in earlier meetings for a particular formulation for a specific company are being again placed before the MDC in case of different applicant. The basic methodology followed in such cases is the same and only the data for calculation

purpose changes. Hence, MDC is of the view that since the basic methodology followed is same and only data of calculation changes, other applications may be placed before it only when there is change in circumstances requiring deliberations.

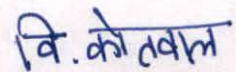
8.2 The Authority deliberated and accepted the recommendation of the MDC. The Authority directed that pricing of subsequent applications of that formulation which has already been placed in MDC once may be done on the methodology adopted by MDC for that formulation. Hence, retail price of such formulation may be worked out and the draft working sheet may be uploaded on the website for comments, if any as is done for other cases of retail price fixation. This will allow MDC to focus on other important issues rather than looking at routine matters.

9. Agenda item no. 9 – Form-IV intimation received from M/s Serum Institute of India Pvt Ltd in respect of 2 scheduled formulations (i) Tetanus Toxoid Injection 0.5ml and (ii) Tetanus Toxoid Injection 5 ml of M/s Serum Institute of India Pvt Ltd.

9.1 The Authority noted that directions under Para 3 of DPCO,2013 were issued to M/s Serum Institute of India Pvt. Ltd. from time to time by the Authority for continued production /sale in respect of 2 scheduled formulations (i) Tetanus Toxoid Injection in 0.5ml pack and (ii) Tetanus Toxoid Injection in 5 ml pack manufactured by M/s Serum Institute of India Pvt. Ltd. The period of continuation of production/sale was extended up to 31.12.2023 in the 105th Authority meeting held on 15.12.2022.

9.2 The Authority deliberated upon the matter in detail and decided to re-invoke Para 3 of DPCO, 2013 to direct M/s Serum Institute of India Pvt. Ltd to continue the production and sales of two scheduled formulations (1) Tetanus Toxoid Injection in 0.5ml pack and (ii) Tetanus Toxoid Injection in 5 ml pack up to 31.12.2024.

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



(Dr. Vinod Kotwal)
Member Secretary