

No.31015/06/2022-Pricing (E-22318)
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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Room No. 207, D Wing, Shastri Bhawan,
New Delhi-110 001.

Order

This is an order disposing of Review Application dated 23.09.2022 filed by M/s Sun Pharma Laboratories Limited (hereinafter called the Applicant) under Para 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) against price fixation order issued vide S.O. No. 4002(E) dated 24.08.2022 by the National Pharmaceutical Pricing Authority (NPPA) in respect of retail price of Acetazolamide IP 500 mg (as an Extended Release) Capsule.

2. Background

After submission of the Review Application, on reference of Department of Pharmaceuticals, NPPA have also submitted their response in the matter and hearing was accorded to both the parties on 21.12.2022.

3. Major contentions raised by the Applicant:

The Applicant has referred to the retail price notification S.O No. 4002 (E) dated 24.08.2022 issued by NPPA for Acetazolamide IP 500 mg (as an Extended Release) Capsule – at Sr. No. 39 and submitted as under:

3.1 While going through the calculation of the Retail Price of Acetazolamide IP 500mg Capsule (as an Extended Release), it appears that inadvertently, ceiling price of Acetazolamide 250mg Capsule of ₹4.53 per capsule vide S.O. 1330 (E) dated 25.03.2021 have been taken into consideration, instead ceiling price of ₹5.02 per capsule vide S.O. 1499 (E) dated 30.03.2022 should have been considered for determining the retail price of the captioned product.

3.2 The working and comparison of Retail price recommended by the Multidisciplinary Committee of Experts based on Pronab Sen Committee Report considering ceiling price of Acetazolamide 250mg

Capsule vide S.O. 1330 (E) dated 25.03.2021 and vide S.O. 1499 (E) dated 30.03.2022 is as under:

S.O. No & Date of Notification	Notified Ceiling Price Per Capsule	Calculation as per Pronab Sen Committee Report	Derived Retail Price Per Capsule
S.O. 1330 (E) Dated 25.03.2021	₹ 4.53	=4.53[1+0.80{(500-250/250)}]	₹ 8.15

S.O. No & Date of Notification	Notified Ceiling Price Per Capsule	Calculation as per Pronab Sen Committee Report	Derived Retail Price Per Capsule
S.O. 1499 (E) Dated 30.03.2022	₹ 5.02	=5.02[1+0.80{(500-250/250)}]	₹ 9.04

Thus, there is a difference of 0.89 per capsule.

3.3 The company has also mentioned that they had filed their representation dated 20.07.2022 to NPPA raising their concerns. However, the NPPA did not accept the company representation in their Authority Meeting held on 05.08.2022. The company has reproduced below the extract on Note 3 of Minutes of the 232nd (overall) and 100th meeting of the Authority under DPCO 2013 held on 05.08.2022.

Note 3. The Authority noted the representation dated 20.7.2022 filed by M/s sun Pharma Laboratories Ltd stating that recommendation of the retail price by the Multidisciplinary Committee of Experts in its 43rd meeting dated 04.07.2022 should be based on the ceiling price of Acetazolamide 250mg capsule as per SO. 1499(E) dated 30.03.2022 (which is applicable from 1st April 2022) instead of ceiling price based on SO. 1330(E) dated 25.03.2021 (which is applicable in November 2021). The Authority deliberated upon the matter in detail and observed that the ceiling price of Acetazolamide 250 mg capsule, as applicable in November 2021, has been considered by the Multidisciplinary Committee of Experts since it is six month prior to date of application made by M/s

Sun Pharma Laboratories Ltd and the same is in line with the provisions of DPCO 2013 regarding the data to be taken for calculation of retail price. Accordingly, the Authority accepted the recommendation of the Committee and approved the retail price of Acetazolamide 500mg (extended release) capsule for M/s Sidmak Laboratories (India) Pvt. Ltd. (Manufacturer) and M/s Sun Pharma Laboratories Ltd (marketer) at Rs. 8.15 per capsule excluding GST

3.4 In response to above, the company has stated as under:

(i) As per para 9(4) of DPCO, 2103, the data available for the month ending immediately before six months of receipt of application, is specified for the new drugs already available in the market.

(ii) The company Retail Price application for the new drug falls under paragraph 15(4) of DPCO, 2013 i.e. “the new drug not available in domestic market” which is Acetazolamide IP 500mg Capsule (as an Extended Release) and we are the first company to launch this product in India.

(iii) Accordingly, its price fixation is to be recommended by the Multidisciplinary Committee of Experts based on formula recommended in the Pronab Sen Committee Report on Ceiling Price of Acetazolamide 250mg Capsule notified by NPPA.

(iv) When the company submitted their Retail Price application on 07.06.2022, NPPA has already notified Ceiling Price of Acetazolamide 250mg Capsule vide S.O. 1499 (E) dated 30.03.2022 at 5.02 per capsule.

(v) By not considering Ceiling Price already notified in March 2022 by NPPA, well before date of the company application, the company is at a loss of ₹ 0.89 per capsule, which cannot be ignored.

3.5 The Applicant has mentioned that the MRP based on retail price fixed by NPPA as per referred notification have already implemented.

3.6 Accordingly, the Applicant has requested to issue necessary directive to NPPA to kindly revise/recalculate the retail price of the product, based on formula recommended in the Pronab Sen Committee Report on Ceiling Price of Acetazolamide 250mg Capsule notified by NPPA vide S.O. 1499 (E) dated 30.03.2022.

4. Gist of clarifications made by NPPA:

4.1 NPPA mentioned as under: -

Sl. No.	Concerns raised in Review Application of M/s Sun Pharma	Comments of NPPA
1.	<p>The retail price of Acetazolamide IP 500 mg (extended release) capsule has been fixed based on the recommendation of the Multidisciplinary Committee by considering the ceiling price of Acetazolamide 250 mg capsule as per SO. 1330(E) dated 25.03.2021 instead on SO. 1499(E) dated 30.03.2022.</p> <p>When we submitted retail price application on 07.06.2022, NPPA has already notified ceiling price of Acetazolamide 250 mg capsule vide SO. 1499(E) dated 30.03.2022.</p>	<p>The application dated 07.06.2022 of M/s Sun Pharma Laboratories Ltd for retail price fixation of Acetazolamide IP 500 mg (extended release) capsule was placed before the Multidisciplinary Committee of Experts since the market-based data was not available. The MDC in its 43rd meeting dated 04.07.2022 recommended the retail price at Rs. 8.15 per capsule excluding GST by applying the formula as specified in the Pronab Sen Committee Report on the ceiling price of Acetazolamide 250 mg capsule as applicable on November 2021 [as per SO. 1330(e) dated 25.03.2021] i.e six month prior to the date of receipt of application.</p> <p>MDC adopted the same approach while recommending the retail price of other formulations. For instance, while recommending the retail price of 'Human Coagulation Factor VIII 1000IU' for M/s Baxalta Bioscience in the same meeting, the Committee considered the ceiling price of 'Human Coagulation factor VIII 250IU' as</p>

		applicable six month prior to the date of receipt of application.
2.	As per para 9(4) of DPCO, 2013, “The market based data for fixing the retail price of new drugs available in the market, shall be the data available for the month ending immediately before six months of receipt of application for fixing the price of the new drug”. Thus, above criteria to consider the data available for the month ending immediately before six months of receipt of application is specified for the new drug already available in the market. Accordingly, its price fixation is to be recommended by the MDC based on formula recommended in the Pronab Sen Committee Report on ceiling price of Acetazolamide 250 mg capsule notified vide S.O. 1499 (E) dated 30.03.2022.	The data of formulation available in market of the same drug but in a different strength (i.e. Acetazolamide 250 mg capsule). The same is used for reference pricing of the said new drug by MDC without altering the period of data to be used for pricing of new drug as contained in DPCO 2013 i.e data of 6 months preceding the month of receipt of application. Use of formula of Pronab Sen Committee is one of the means / methods considered for pricing by MDC for arriving at a price of a new drug, the data of which was available in the market for the strength other than the applied strength of new drug.

4.2 Accordingly, based on the recommendation of the MDC, the Authority approved the retail price of Acetazolamide 500mg (extended release) capsule for M/s Sidmak Laboratories (India) Pvt. Ltd. (manufacturer) and M/s Sun Pharma Laboratories Limited (marketer) at Rs. 8.15 per capsule (excluding GST) and the price was notified vide SO. 4002(E) dated 24.08.2022.

4.3 In view of the above, the review application of M/s Sun Pharma Laboratories Ltd is not tenable and may be treated as closed.

5. Examination:

5.1 Under DPCO 2013, Para 9 states about the "Reference data and source of market based data". Para 9 (4) states, "The market based data for fixing the retail price of new drugs available in the market, shall be the data available for the month ending immediately before six months of receipt of application for fixing the price of the new drug".

5.2 The data of formulation available in market of the same drug but in a different strength (i.e. Acetazolamide 250 mg capsule) is used for reference pricing of the said new drug by MDC without altering the period of data to be used for pricing of new drug as contained in DPCO 2013 i.e data of 6 months preceding the month of receipt of application.

5.3 MDC adopted the same approach while recommending the retail price of other formulations.

6. Decision:

The action of NPPA fixing the Retail prices of the formulation Acetazolamide IP 500 mg (as an Extended Release) Capsule of M/s Sun Pharma Laboratories Limited vide S.O. No.4002(E) dated 24.08.2022 is upheld and the review application under consideration is, accordingly, rejected.

Issued on this, the 9th day of February, 2023.



(Awadhesh Kumar Choudhary)

Sr. Economic Adviser to the Government of India
[For and on behalf of the President of India]

To:

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Copy to:

1. Chairperson, NPPA, New Delhi
2. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi
3. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi
4. Technical Director, NIC for uploading the order on DoP's Website.
5. Guard File