

No. 31015/09/2017-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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**A- Wing, Shastri Bhawan,
New Delhi 110 001**

Subject: Review application of M/s Sun Pharmaceutical Industries Ltd. against price fixation of "Trypsin48 mg + Bromelain 90 mg + Rutoside Trihydrate BP 100 mg + Diclofenac Sodium IP 50mg." vide NPPA order No. S.O. 4131(E), dated 22.12.2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref:

- 1) Review application dated 17.01.2017
- 2) NPPA notification under review S.O. 4131(E), dated 22.12.2016
- 3) Record Note of discussions held in the personal hearing held in the matter on 30.05.2017.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Sun Pharmaceutical Industries Ltd. (hereinafter called the petitioner) against notification S.O. No.4131(E), dated 22.12.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Trypsin48 mg + Bromelain 90 mg + Rutoside Trihydrate BP 100 mg + Diclofenac Sodium IP 50mg.

2. The petitioner has contended as under:-

- I. Working sheet uploaded on NPPA website dated 23.12.2016 suggested to have considered 15 packs in the retail price calculation. It is observed that 1 pack viz. TRYBR-D 48/100/90/50MG TABLET 10 of M/s INDOCO REMEDIES LTD has been captured in the calculation despite having market share less than 1%.
- II. Further, company referred to this Department's order dated 10.01.2017 in respect to Review Application with File No. 31015/73//2016-PI.I. It is apparent that retail price fixed for captioned formulation is not in line with the stated order dated 10.01.2017.
- III. Further, company referred to Notification S.O. 4131 (E), wherein two details are appearing ambiguous. Table title column No. 2 mentioned as Scheduled Formulation, and footnote (f) where its suggested to furnish quarterly return to NPPA in respect of production/import and sale of product in Form-III of Schedule-II of DPCO 2013. They submitted that the captioned formulation is a Non-Scheduled Formulation, and hence applicability of Form-III, Form IV does not stand appropriate in this case. Therefore, term Scheduled Formulation, and footnote (f) should be removed for transparent instruction and compliance.

IV. In view of the above, company requested this Department to kindly issue necessary directives to NPPA to re-notify the ceiling price of the above said formulation and make necessary modification in notification.

3. **Comments of NPPA:**

In this regard, it is mentioned that retail price of Rs. 14.44 per tablet for **Volitra Enzo Tablet** was notified vide S.O. 4131(E) dated 22.12.2016 as per para 5, 11, & 18 under DPCO 2013.

2. Company has stated that correct methodology was not followed in arriving at the retail price for **Volitra Enzo Tablet**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013 and as per the decisions of 39th Authority meeting held on 21.12.2016. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has pointed out that NPPA has considered the PTR of TRYBR-D of M/s Indoco Remedies Ltd. despite having market share less than 1%.	<p>NPPA has fixed the retail price for Volitra Enzo Tablet as per the data provided by pharma-trac for the month of February, 2016 as per the decision of 27th Authority Meeting held on 29.3.2016.</p> <p>DOP vide letter no. F. No. 31015/44/2016-PI.I dated 11.7.2016 gave the following, directions: "<i>NPPA to henceforth place a draft version of the Price Calculation Sheets for the proposed revised price notification, including wherever applicable, the Price to Retailer (PTR) and Moving Annual Turnover (MAT) values adopted for calculations, on the website of NPPA for 10 clear working days to invite comments from the affected pharmaceuticals firms. Only after taking into account the comments or any additional data thus received within the given time period, the NPPA shall finalize the Ceiling and the Retail Prices. This issues with the approval of Hon'ble Minister (Chemicals & Fertilizers)</i>". Accordingly, NPPA uploaded draft working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. M/s Sun Pharma Industries Limited did</p>

		<u>not make any representation against the proposed retail price uploaded on NPPA's website.</u>
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3. Company has not challenged any notification in respect of **Volitra Enzo Tablet** in the Court.

5. Examination:

The petitioner company has challenged the NPPA Order S.O. 4131(E), dated 22.12.2016 for price fixation of their product brand name "**Volitra Enzo Tablet**" containing formulation **Trypsin48 mg + Bromelain 90 mg + Rutoside Trihydrate BP 100 mg + Diclofenac Sodium IP 50mg.** on the ground that one pack, namely, TRYBR-D 48/100/90/50MG tablet 10's pack of INDOCO REMEDIES LTD., which is having less than 1% market share, should be excluded from price fixation. It is seen from the calculation sheet that NPPA has clubbed the market share of two Brands of Indoco Remedies Ltd. DPCO does not recognize a company for average PTR but only medicines / formulations. Hence, NPPA has wrongly considered the PTR of TRYBR-D 48/100/90/50MG tablet 10's pack, having only 0.74% share. Therefore, NPPA may be directed to consider only those medicines / formulations having MAT value of more than 1% market share.

Further, as the product of the petitioner company is a 'new drug', and is not a scheduled formulation, the word 'scheduled formulation' should be removed from the column (2) of Table in SO No.4131(E), dated 22nd December, 2016. As per Schedule II of DPCO, 2013, Form III & Form IV are to be filled up for scheduled formulations only. Hence, Note (f) of the notification also needs to be removed.

In view of the above, NPPA should be directed to revise/refix the retail price of "**Volitra Enzo Tablet**" containing formulation **Trypsin48 mg + Bromelain 90 mg + Rutoside Trihydrate BP 100 mg + Diclofenac Sodium IP 50mg.** by considering only those medicines / formulations having MAT value of more than 1% market share, as DPCO does not recognize a company for average PTR but only medicines / formulations. Further, the word 'scheduled formulation' in Column (2) of Table and Note (f) of the notification should also be removed for this product, since the subject product is a 'new drug'.

6. Government Decision:

"NPPA is hereby directed to revise/refix the retail price of "Volitra Enzo Tablet" containing formulation Trypsin48 mg + Bromelain 90 mg + Rutoside Trihydrate BP 100 mg + Diclofenac Sodium IP 50mg. by considering only those medicines / formulations having MAT value of more than 1% market share, as DPCO does not recognize a company for average PTR but only medicines / formulations.

“NPPA is further directed to remove the word ‘scheduled formulation’ in Column (2) of Table and Note (f) of the notification for this product, since the subject product is a ‘new drug’.

Issued on this date, the 27th day of August, 2017.

(M.K. Bhardwaj)
Deputy Secretary
For and on behalf of the President of India

To

1. M/s. Sun Pharmaceutical Industries Ltd.,
8-C, 8th Floor, Hansalya Building,
15, Barakhamba Road, Connaught Place,
New Delhi-110 001.
2. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001

Copy to :

1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
3. T.D., NIC for uploading the order on Department's Website