

No. 31015/45/2018-Pricing
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

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A- Wing, Shastri Bhawan,
New Delhi 110 001

Order

1. This is an order on a review application, dated 30.11.2018, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Sun Pharma Laboratories Ltd. (hereinafter called the applicant) against notification S.O. No.5638(E), dated 02.11.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the retail price of Baclofen Oral Solution.

2. The applicant has contended as under:-

2.1 Retail price of subject formulation was notified as Rs 1.42 per ml vide SO 5638(E) dated 02.11.2018 however working sheet for this notification was displayed on NPPA website on 13.11.2018. Draft working sheet was not made available prior to price notification.

2.2 The Official Central GST rate notified for Baclofen is 2.5 % making the effective GST rate as 5 % combining equal central and state share. The claimed MRP mentioned in their Form I application of this formulation was Rs 160 for 100ml pack. In working sheet GST of 12% was factored into calculation of erroneously arrived claimed retail price of Rs 1.42 per ml which otherwise would have been different had official 5% GST would have been considered.

2.3 The applicant stated that in the notification on website of CBEC, the list of goods at 5% GST rate is given, wherein Baclofen is mentioned at S.No.5 in list 1 of Schedule I describing goods charged at 5% GST rate.

2.4 Applicant, therefore, requested to revise the retail price of Baclofen Oral Solution by considering 5% GST.

3. Comments of NPPA:

3.1 Based on para 5 and 15 of DPCO 2013, NPPA presently uploads the working sheet, if applicable, after notification of the retail price.

3.2 NPPA has noted the issue raised by the applicant and the same may be looked into based on the direction of DoP and submission of the requisite documents by the applicant.

4. Examination:

NPPA fixed the retail price of formulation of M/s Sun Pharmaceutical Industries Ltd. vide SO 5638(E), dated 02.11.2018. While calculating the retail price of the formulation, NPPA has factored 12% GST.

4.2 In the notification on website of CBEC, the list of goods at 5% is given wherein Baclofen is mentioned at S.No.5 in list 1 of Schedule I, describing the 2.5% goods. Thus, the claim of the applicant that effective GST rate for Baclofen is 5% combining equal central and state share, has got merit.

4.3 It is pertinent to mention that Department of Pharmaceuticals, vide its OM F.No.31015/44/2016-PI.I had instructed NPPA to place a draft version of the price calculation sheets for the proposed revised price notifications, 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 pharmaceutical firms. NPPA was expected to finalise the ceiling and retail prices only after taking into the account the comments or any additional data thus received within the given time period. Had NPPA followed the above mentioned O.M. while fixing retail price of this formulation and had uploaded the working sheet on its website before notifying the retail price, the applicant could have brought this error in calculation to NPPA's notice and NPPA could have rectified the error itself and applicant need not have taken recourse to filing a review application.

4.4 In view of the fact that retail price of subject formulation was fixed considering an inapplicable GST rate, NPPA needs to refix the retail price of Baclofen Oral Solution after factoring effective 5% GST rate.

5. Decision:

NPPA is hereby directed to refix the retail price of Baclofen Oral Solution after factoring effective (5%) GST rate, within a period of one month from the date of issue of the order.

Issued on this date, the 10th day of January, 2019.

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

Copy to :-

1. M/s Sun Pharma Laboratories Ltd., 8-C, 8th Floor, Hansalaya 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
3. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
4. PS to MoS (C&F), Shastri Bhawan, New Delhi for information.
5. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
6. T.D., NIC for uploading the order on Department's Website