

No. 31015/22/2018-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 an application dated 05.03.2018 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Sun Pharma Laboratories Limited (hereinafter called the applicant) against notification S.O. No. 544(E), dated 06.02.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Tigatel Ch-40; Tigatel Ach-40; Tigatel Ach-80 and Naxcom.

2. The applicant has contended as under:-

Tigatel CH-40:

In working sheet of Tigatel CH-40 tablet uploaded on NPPA website on 05.03.2018, December 2016 MAT value of product namely ERITEL CH-40/12.5MG TABLET 15 of M/s. ERIS LIFESCIENCES PVT. LTD. is captured incorrectly. MAT December 2016 of ERITEL CH-40/12.5MG TABLET 15 is Rs. 17,75,44,122.33 as per Pharmatrac data available with the company, however same is erroneously captured as Rs.17,77,31,426.80 in Retail Price calculation.

Tigatel ACH-40:

In working sheet of Tigatel ACH-40 tablet uploaded on NPPA website, product namely TELMA ACT 12.5/40/5 MG TABLET 10 of M/s. GLENMARK PHARMACEUTICALS LTD. was not appearing. MAT February 2017 of TELMA ACT 12.5/40/5 MG TABLET 10 is Rs. 14,80,783.47 and market share is more than 1% as per Pharmatrac data available with the company, however same is missing in Retail Price calculation.

Tigatel ACH-80:

In working sheet of Tigatel ACH-80 tablet uploaded on NPPA website, April 2017 MAT value of product namely ELDOTEL TRIO 80/5/12.5 MG & ERITEL CH TRIO 80/5/12.5 MG of M/s. EL-DORADO BIO-TECH PVT LTD & M/s. ERIS LIFE SCIENCES PVT LTD. respectively, have been captured incorrectly. MAT April 2017 of ELDOTEL TRIO 80/5/12.5 MG is Rs. 411,168.01 and of ERITEL CH TRIO 80/5/12.5 MG tablet is Rs. 79,77,311.16 as per Pharmatrac data available with the company, however same is erroneously captured as Rs.411,620.85 & Rs.79,77,688.32 respectively in Retail Price calculation.

Naxcom:

In working sheet of Naxcom tablet uploaded on NPPA website, January 2017 market share of product namely SNAPIT 85/500 MG TABLET 2 of M/s. ABBOTT INDIA LTD. is captured incorrectly. Market share for January 2017 of SNAPIT 85/500 MG TABLET 2 is more than 1% as per Pharmatrac data available with the company, however same is erroneously captured at 0,60% in Retail Price calculation.

2.2 In view of above, company requested to issue necessary directive to NPPA to revise the retail price of captioned formulations.

3. Comments of NPPA:

3.1 The ceiling price of formulation fixed by NPPA, vide S.O. No. 544 (E) dated 06.02.2018 is detailed below:-

Name of the Formulation	Company's Product Composition	Notified Price (Rs)
Tigatel CH 40	Each Film coated tablet contains: Telmisartan IP 40mg Clorthalidone IP 12.5 mg	7.64
Tigatel ACH 40	Each Film coated tablet contains: Telmisartan IP 40mg Amlodipine 5mg Clorthalidone IP 12.5 mg	8.75
Tigatel ACH 80	Each Film coated tablet contains: Telmisartan IP 80mg Amlodipine 5mg Clorthalidone IP 12.5 mg	14
Naxcom	Each Uncoated bilayer tablet contains; Sumatriptan IP 40mg Naproxen Sodium USP 500mg	30

3.2 NPPA fixed retail price of Tigatel CH 40 as Rs.8.75 per tablet; Tigatel ACH 40 as Rs.7.64 per tablet; Tigatel ACH 80 as Rs.14.00 per tablet and Naxcom tablet as Rs.30.00 per tablet vide S.O. 544 (E) dated 06.02.2018 based on Pharmatrac data.

4. Examination:

Tigatel CH-40:

Company submitted copy of Pharmatrac data in respect of formulation Tigatel CH-40, wherein the MAT value of product ERITEL CH 40 of M/s Eris Life Sciences Pvt. Ltd. is shown as Rs.17,75,44,122.33. As per Pharmatrac data, uploaded by NPPA on its website, for the formulation, the MAT value is taken as Rs.17,77,31,426.80. It is observed from the calculation sheet, the market share of the product is 17.68%. The difference in MAT value provided by the company and considered by NPPA is only around Rs.2 lakhs, which does not make much difference in market share of the product, resultantly not making any impact on retail price fixation.

The basic purpose of filing review application is against wrong fixation of retail price of any formulation. The company should raise objection if the difference in MAT value considered by NPPA is making any major impact on market share, which is resulting into wrong fixation of market share of the product. The objection raised by the company is not worth consideration and should be ignored.

Tigatel ACH 40

Company submitted copy of Pharmatrac data in respect of formulation containing Telmisartan 40mg+Amlodipine 5mg+Clorthalidone12.5mg, wherein the MAT value of product TELMA ACT of M/s Glenmark Pharmaceuticals Ltd., containing above combination, is shown as Rs.14,80,783.47. It is seen from the calculation sheet uploaded by NPPA on its website, the product of M/s Glenmark Pharmaceuticals Ltd. is not appearing. The total MAT value of the product is Rs.2,23,79,215/-. Hence, the market share of the product of M/s Glenmark Pharmaceuticals Ltd. appears to be around 6%.

In view of the above, NPPA needs to verify the market share of the product TELMA ACT (containing Telmisartan 40mg+Amlodipine 5mg+Clorthalidone12.5mg) of M/s Glenmark Pharmaceuticals Ltd. and refix the retail price of Tigatel ACH-40 by including the PTR of TELMA ACT in retail price calculation, on merit.

Tigatel ACH-80

Company submitted copy of Pharmatrac data in respect of formulation containing Telmisartan 80mg+Amlodipine 5mg+Clorthalidone12.5mg, wherein the MAT value of product ELDOTEL TRIO 80/5/12.5MG of M/s El-Dorado Bio-Tech Pvt Ltd is shown as Rs 4,11,168.01. Company stated that NPPA considered MAT value as Rs.4,11,620.85. Similarly, for product ERITEL CH TRIO 80/5/12.5MG of M/s Eris Lifesciences Pvt Ltd., the MAT value is Rs.79,77,311.16, whereas NPPA captured MAT value as Rs.79,77,688.32 in retail price calculation.

The difference in MAT value provided by the company and considered by NPPA is very meagre, which does not make much difference in market share of the product, resultantly not making any impact on retail price fixation. The objection raised by the

company is not worth consideration and should be ignored. Raising irrelevant objections, which are of no importance, is not in good taste. The company should desist from raising such type of objections in its review application.

Naxcom:

On perusal of copy of Pharmatrac data submitted by company in respect of formulation containing Sumatriptan 85mg+Naproxen Sodium 500mg, the MAT value of product SNAPIT of M/s Abbott India Ltd., containing above combination for the month of January,2017, is shown as Rs.5,58,877.60. It is seen from the calculation sheet uploaded by NPPA on its website, the market share of MAT value (Rs.5,58,877.60) of the product SNAPIT of M/s Abbott India Ltd. comes to only 0.60% of the total MAT value. Hence, not considering the PTR of Abbott product by NPPA is in order. Therefore, the objection raised by the applicant company has got no merit.

5. Decision:

“NPPA is hereby directed to verify the market share of the product TELMA ACT (containing Telmisartan 40mg+Amlodipine 5mg+Clorthalidone 12.5mg) of M/s Glenmark Pharmaceuticals Ltd. and refix the retail price of Tigatel ACH-40 by including the PTR of TELMA ACT in retail price calculation, on merit, within a period of thirty days from the issue of this order”

“The objections raised by the applicant company in respect of its formulations Tigatel CH-40, Tigatel ACH-80 and Naxcom are irrelevant and stands rejected.”

Issued on this date, the 26th day of June, 2018.

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

Copy to:-

1. M/s Sun Pharma Laboratories Limited, 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.