

No. 31015/37/2018-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 10.7.2018 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.2398(E), dated 12.06.2018 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling prices of Triolmezest CH 20 tablets (containing Olmesartan IP 20mg+Amlodipine Besylate IP eq. to Amlodipine 5mg+Chlorthalidone IP 12.5mg) and Triolmezest CH 40 tablets (containing Olmesartan IP 40mg+Amlodipine Besylate IP eq. to Amlodipine 5mg+Chlorthalidone IP 12.5mg). M/s Sun Pharmaceutical Industries Limited also filed review application dated 10.07.2018 on the similar issue in respect of its formulation Rosuvas CV 10 (containing Rosuvastatin calcium eq. to Rosuvastatin 10mg+Clopidogrel Bisulphate eq. to Clopidogrel 75mg). Since the substantial issue and arguments raised by both the companies are same, the review applications of both the companies are disposed of by this order.

2. The companies have contended as under:-

M/s Sun Pharma Laboratories Limited:

Retail price for Triolmezest CH 20 tablets, Triolmezest CH 40 tablets were notified as Rs. 8.78/- per tablet and 15.53/- per tablet respectively vide NPPA SO 2398(E) dated 12.06.2018. Working sheet for this notification was made available on NPPA website only on 25.06.2018. Company could get to know about this calculation anomaly through this working sheet only.

It is evident from working sheet that the market data of July 2017 were used in retail price computation. Additionally a factor of 0.95905 was incorporated in arriving final retail price as Rs. 8.78/- per tablet for Triolmezest CH 20, and as 15.53/- per tablet for Triolmezest CH 40.

It is pertinent to note that GST rate was made effective from 01.07.2017 and in captioned retail price computation market data of July 2017 was considered wherein already post GST PTR were appearing. However, in instant case GST rate was factored additionally @ 0.95905% in the calculation which appears to be erroneous, details of which are mentioned below:

Product	Retail Price based on July 2017 data (Per Tablet)	Final retail price by factoring 0.95905 (Per Tablet)
Triolmezest CH 20	Rs. 9.15	Rs. 8.78
Triolmezest CH 40	Rs. 16.19	Rs. 15.53

In view of above submission, company requested this Department to issue necessary directive to NPPA to re-notify the retail price of captioned formulations by excluding the additionally incorporated factor of 0.95905.

M/s Sun Pharmaceutical Industries Limited

Retail price for Rosuvas CV 10 was notified as Rs. 10.96/- per tablet via NPPA SO 2398 (E) dated 12.06.2018. Working sheet for this notification was made available on NPPA website only on 25.06.2018. Company could get to know about this calculation anomaly through this working sheet only.

It is evident from working sheet that the market data of July 2017 were used in retail price computation. Additionally a factor of 0.95905 was incorporated in arriving final retail price as Rs. 10.96/- per tablet for Rosuvas CV 10.

It is pertinent to note that GST rate was made effective from 01.07.2017 and in captioned retail price computation market data of July 2017 was considered wherein already post GST PTR were appearing. However, in instant case GST rate was factored additionally @ 0.95905% in the calculation which appears to be erroneous, details of which are mentioned below:

Product	Retail Price based on July 2017 data (Per Tablet)	Final retail price by factoring 0.95905 (Per Tablet)
Rosuvas CV 10	Rs. 11.43	Rs. 10.96

In view of above submission, company requested this Department to issue necessary directive to NPPA to re-notify the retail price of captioned formulations by excluding the additionally incorporated factor of 0.95905.

3. Comments of NPPA:

NPPA has noted the issue raised by the companies and the same may be reviewed based on the direction given by DoP.

4. Examination:

4.1 GST rate was made effective from 01.07.2017. NPPA considered the market data of July 2017 for retail price computation, wherein GST rate was already factored in the data. However, NPPA erroneously again factored GST rate in the calculation.

4.2 In view of the above, the grievance raised by the companies in their review applications got merit. Therefore, NPPA may be directed to revise the retail prices of the formulations Triolmezest CH 20 tablets (containing Olmesartan IP 20mg + Amlodipine Besylate IP eq. to Amlodipine 5mg + Chlorthalidone IP 12.5mg) and Triolmezest CH 40 tablets (containing Olmesartan IP 40mg + Amlodipine Besylate IP eq. to Amlodipine 5mg + Chlorthalidone IP 12.5mg) [of Sun Pharma Laboratories Limited] and Rosuvas CV 10 (containing Rosuvastatin calcium eq. to Rosuvastatin 10mg + Clopidogrel Bisulphate eq. to Clopidogrel 75mg) [of Sun Pharmaceutical Industries Limited], without factoring additional GST @ 0.95905%.

5. Decision:

“NPPA is hereby directed to revise the retail prices of the formulations Triolmezest CH 20 tablets (containing Olmesartan IP 20mg+Amlodipine Besylate IP eq. to Amlodipine 5mg+Chlorthalidone IP 12.5mg) and Triolmezest CH 40 tablets (containing Olmesartan IP 40mg+Amlodipine Besylate IP eq. to Amlodipine 5mg+Chlorthalidone IP 12.5mg) [of Sun Pharma Laboratories Limited] and Rosuvas CV 10 (containing Rosuvastatin calcium eq. to Rosuvastatin 10mg+Clopidogrel Bisulphate eq. to Clopidogrel 75mg) [of Sun Pharmaceutical Industries Limited], without factoring additional GST @ 0.95905%., within fifteen days of issue of this order.”

Issued on this date, the 4th day of September, 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-110001.
2. M/s Sun Pharmaceutical Industries Limited, Sun House, Plot No.201 B/1, Western Express Highway, Goregaon (E), Mumbai-400 063.
3. Member Secretary, National Pharmaceutical Pricing Authority, YMCA Cultural Centre Building, 1, Jai Singh Road, New Delhi-110001
4. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.
5. PS to MoS(C&F), Shastri Bhawan, New Delhi for information.
6. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.
7. T.D., NIC for uploading the order on Department's Website