

No. 31015/18/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

A Wing, Shastri Bhavan,
New Delhi 110 001

Order

1. This is an order on the application dated 03.03.2017, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Sanofi-Synthelabo (India) Private Limited (hereinafter called the applicant) against notification S.O. No.443(E), dated 14.2.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Amiodarone Injection - 50mg/ml. This order is being issued in supersession of the earlier order No.31015/18/2017-Pricing, dated 10.10.2017 issued by the department on the instant review application.

2. In the review application, the applicant claimed that it has marketed Cordarone Injection 3ml, containing Amiodarone 50mg/ml and has Moving Annual Turnover (MAT) of Rs.5.8 crores as of August, 2015 and PTR was Rs.56.90 per 3ml, i.e. Rs.18.97 per ml. The company stated that its formulation was not considered while fixing the ceiling price of Amiodarone Injection – 50mg/ml.

3. The matter was examined in Department of Pharmaceuticals and the claim of the company was not considered as NPPA stated that the data of the product was not reflecting in Pharmatrac data. NPPA had fixed the ceiling price Amiodarone Injection – 50mg/ml vide SO 443(E), dated 14.02.2017, considering the data of products being manufactured by M/s Torrent Pharmaceuticals Ltd. and applied monopoly reduction. NPPA stated that M/s Sanofi-Synthelabo (India) Private Limited could not submit the sample of Cardarone injection and also satisfy the requirement of their product being manufactured in August, 2015. NPPA further stated that M/s Torrent has not made any representation against the price fixation of Amiodarone 50mg/ml Injection.

4. Based on the above facts, the review application was disposed of by the Department of Pharmaceuticals vide Review Order of even number, dated 10th October, 2017, with the following decision:-

“The grievances raised by M/s Sanofi-Synthelabo (India) Private Limited in their review application cannot be reconsidered and hence the application stands rejected.”

5. The company filed a representation, dated 23rd October, 2017 against DoP’s review order, dated 10.10.2017, requesting to re-consider and re-examine the review order.

6. The company, in support of its claim of having sufficient market share of its product, furnished the IMS data. The matter was taken-up with AIOCD Pharmasofttech AWACS Pvt. Ltd. (hereinafter called Pharmatrac). Thereafter, Pharmatrac confirmed that Cardarone was

sold in market as 150mg in pack of 3ml (50mg/ml) and was having MAT value of Rs.6.6 crores, with the highest market share as on August, 2015, against the MAT value of Rs.0.2 crores of M/s Torrent Pharmaceuticals Limited.

7. NPPA had fixed the ceiling price of Amiodarone 50mg/ml by considering the brand Ritebeat of M/s Torrent Pharmaceuticals Limited only under para 6(i) of DPCO, 2013 and applied monopoly reduction. The product Cardarone (containing Amiodarone 50mg), being marketed by M/s Sanofi-Synthelabo (India) Private Limited, was also available in the market in August, 2015. Hence, the ceiling price of Amiodarone 50mg should have been fixed under para 4(1) of DPCO, 2013, by considering the products of both the companies.

8. **In view of paras 6&7 above, the entire calculations needs to be done afresh by NPPA considering the fresh/updated Pharmatrac data with the correct situation. Accordingly, review application dated 03.03.2017 is accepted. NPPA is hereby directed to re-fix the ceiling price of Amiodarone 50mg/ml Injection under para 4(1) of DPCO, 2013, by also considering the MAT value and PTR of Cardarone (containing Amiodarone 50mg) within a period of thirty days of issue of this order.**

This is issued with the approval of Competent Authority.

Issued on this, the 29th day of May, 2018.

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

Copy to :

1. **M/s. Sanofi-Synthelabo (India) Private Limited, Sanofi House, CTS No.117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai-400 072.**
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**