

No.31015/07/2019-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 disposing of a review application dated 27.03.2019, filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Zydus Healthcare Limited (hereinafter called the applicant) against notification S.O. No.1028(E), dated 26.02.2019 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Tiotropium Inhalation (MDI) 9 mcg/dose.

2. The main contentions of the applicant are that –

(i) NPPA has made available the working sheet towards the Ceiling Price of Tiotropium Inhalation (MDI) 9 mcg/dose only on 12.3.2019. While going through the working sheet, the applicant observed that the brand Tiomist HFA 9mcg inhaler manufactured by Cadila Healthcare Limited (CHL), Zydus Cadila Group, does not feature at all. As on August 2015 CHL was manufacturing and marketing the said brand in India.

(ii) CHL had filed a scheme of arrangement for transfer of the India Human Formulation Undertaking to its wholly owned subsidiary Zydus Healthcare Limited (ZHL) with National Company Law Tribunal (NCLT) Bench at Ahmedabad, on a going concern basis, by way of slump sale. NCLT had passed an order in the matter of scheme of arrangement for transfer of the Indian Human Formulation Undertaking to Zydus Healthcare Limited on 18.5.2017. NPPA was informed about the said NCLT order vide ZHL letter No. NPPA/ZHL/2017/0307 dated 3.7.2017.

(iii) The applicant further stated that –

(a) Tiomist HFA 9mcg Inhaler was manufactured and marketed by CHL, Zydus Cadila as of August, 2015.

(b) Tiomist HFA 9mcg Inhaler is manufactured and marketed by ZHL, Zydus Cadila w.e.f. 18.5.17.

(c) The AWACS data of August 2015 shows that Tiomist HFA 9mcg Inhaler of Zydus Cadila has MRP of Rs. 400.31, PTR of 311.29, MAT Value of 1.35 as of August 2015 and a Market share of 6%.

(d) NPPA in its working sheet made available on 12.3.2019 has not considered the said brand having market share of 6%. It should have

been considered because CHL, Zydus Cadila was manufacturing and marketing the said brand in August 2015. While this is also a fact that the said brand is now being manufactured and marketed by ZHL, Zydus Cadila and features in the latest AWACS data.

(iv) The applicant requested this Department to advise/direct the NPPA to correct the ceiling price of Tiotropium Inhalation (MDI) 9mcg/dose after considering the correct PTR of brand Tiomist HFA 9mcg Inhaler.

3. NPPA's comments:

NPPA has notified the revised ceiling price considering the data submitted by the concerned companies. Company was informed vide letter No 20(141)/2016/DP/NPPA/Div II dated 06.09.2018 stating that M/s Zydus Cadila did not submit the data with respect to Tiomist 9mcg MDI. Accordingly, NPPA has considered the data submitted by the concerned companies.

4. Examination:

NPPA fixed the ceiling price of Tiotropium Inhalation (MDI) 9mcg/dose vide price notification SO 1028(E), dated 26.02.2019 by considering the data collected from Metered Dose Inhalation (MDI) manufacturing companies for the month of August, 2015, and considered the data of four companies, viz. Cipla Ltd., Glenmark Pharmaceuticals Ltd., Lupin Ltd. and Macleods Pharmaceuticals Pvt. Ltd. NPPA did not consider the data in respect of product Tiomist 9mcg MDI on the ground that M/s Zydus Cadila has not submitted the data with respect to the said product.

4.2 M/s Zydus Healthcare Limited (ZHL) started the manufacturing and marketing of Tiomist 9mcg MDI w.e.f. 18.5.2017, after passing an order in the matter of scheme of arrangement for transfer of the Indian Human Formulation Undertaking to Zydus Healthcare Limited by National Company Law Tribunal. Till then, the said product was being manufactured and marketed by M/s Cadila Healthcare Limited (CHL). It means, the data of the said product for the month of August, 2015 was available with CHL and not with ZHL. The market share of CHL was 6% in the month of August, 2015. The applicant submitted documentary proof in support of its claim.

4.3 In view of the above, NPPA needs to refix the ceiling price of Tiotropium Inhalation (MDI) 9mcg/dose by also considering the PTR of Tiomist 9mcg MDI being manufactured and marketed by M/s Cadila Healthcare Limited for the month of August, 2015, in addition to the data of other MDI manufacturing companies.

5. Decision:

NPPA is hereby directed to refix the ceiling price of Tiotropium Inhalation (MDI) 9mcg/dose by also considering the PTR of Tiomist 9mcg MDI being manufactured and marketed by M/s Cadila Healthcare Limited for the month of August, 2015, in addition to the data of other MDI manufacturing companies.

Issued on this, the 21st day of June, 2019.

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

Copy to :-

1. M/s Zydus Healthcare Limited, Zydus Tower, Satellite Cross Roads, Ahmedabad-380015.
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. Joint Secretary(Pharma), Shastri Bhawan, New Delhi for information.
7. T.D., NIC for uploading the order on Department's Website.