

No. 31015/54/2017-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 27.04.2017 filed under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) by M/s Lupin Limited (hereinafter called the applicant) against notification S.O. No. 1039(E), dated 01.04.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) revising the ceiling prices of Budesonide (A) + Formoterol (B) [Inhalation (MDI/DPI) 400 MCG(A)+6MCG(B); 200MCG(A)+6MCG(B) and 100MCG(A)+6MCG(B)] and Tiotropium Inhalation (DPI) 18MCG/Dose), as per Annual Wholesale Price Index (WPI). M/s Glenmark Pharmaceuticals Limited had also filed a review application on the similar issue, which was examined in DoP and Review Order No.31015/52/2017-Pricing, dated 30th October, 2017 has already been issued.

2. The applicant has contended as under:-

- (i) The Ceiling Price applicable to MDI has also been made applicable to DPI formulations for the formulation at Serial no. 87, 88, 89 & 629 i.e. Budesonide (A) + Formoterol (B) {Inhalation (MDI/DPI) 400 mcg, 200 mcg and 100 mcg} and Tiotropium vide S.O. No. 1039(E) dated 01/04/2017.
- (ii) NPPA announced the prices for the 1st time for formulations listed in Serial no. 87, 88 & 89 (Budesonide + Formoterol) on 27th April 2016 and the Unit is mentioned as "Each Metered Dose". Metered Dose is referred to formulations based on MDI (Metered Dose Inhalation). The work sheet for prices notified on 27th April 2016 also confirms that working has been done based on MDI formulations only. Similarly for formulation listed in Serial No 629 (Tiotropium), NPPA had notified Ceiling Price on 9th May 2016, Sr. No. 36, the unit indicates as "Each Metered Dose". Worksheet also indicated the same as MDI as only MDI formulations prices have been considered for working out Ceiling Price.
- (iii) However, in the notification under reference Dosage form & strength, DPI has been incorporated in serial no. 87, 88 & 89 and the unit has been changed as "1 Dose". Similarly in serial no. 629 MDI has been substituted with DPI and the unit has been indicated as "1 Dose".
- (iv) Company further mentioned that both the formulations are completely different. MDI means Metered Dose Inhalation, which comes in AEROSOL form. DPI means Dry Powder Inhalation, which comes in the form of CAPSULES. For administration, AEROSOL is actuated directly in the patient's mouth for inhalation. However in case of DPI, the capsules are broken in a

special device, and the patient inhales the dry powder from the device by placing the same in mouth. Further the method of administration is decided by the Doctors depending on patient's medical requirement. The manufacturing license granted is also different for both dosages. Additionally, the process of manufacturing is also completely different. Company had sent a representation to NPPA to rectify the error in the notification. Since the same has not been rectified till date, Company filed under Para 31 of DPCO, 2013 for necessary correction. Company submitted that they have implemented the notified prices for their MDI range of formulations.

3. **Comments of NPPA:**

Ceiling price of Budesonide (A) + Formoterol (B) {Inhalation (MDI/DPI) 400 mcg, 200 mcg and 100 mcg} and Tiotropium was notified as Rs.2.79 for Budesonide 400 mcg and Formoterol 6mcg, Rs. 2.23 for Budesonide 200 mcg and Formoterol 6mcg, Rs.1.77 for Budesonide 100 mcg and Formoterol 6mcg and Rs.2.34 for Tiotropium 18 mcg/dose and Rs. 2.20 for Tiotropium 19 mcg/dose vide S.O. 1039(E) dated 01.04.2017 and revised to Rs.2.68 for Budesonide 400 mcg and Formoterol 6mcg, Rs. 2.14 for Budesonide 200 mcg and Formoterol 6mcg, Rs.1.70 for Budesonide 100 mcg and Formoterol 6mcg and Rs.2.24 for Tiotropium 18 mcg/dose and Rs.2.11 for Tiotropium 19 mcg/dose vide S.O. 2058(E) dated 30.06.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

3.2 The company has stated that correct methodology was not followed in arriving at the ceiling price of Budesonide (A)+ Formoterol (B) { Inhalation (MDI/DPI) 400 mcg, 200 mcg and 100 mcg} and Tiotropium. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has stated that vide S.O. 1039(E) dated 01.04.2017, NPPA revised the ceiling price of above mentioned formulations taking into account the WPI value of the calendar year 2016 and that dosage form is not in line with what was mentioned with the original notification. Ceiling price applicable to MDI has also been made applicable to DPI formulations. NPPA for the first time announced the price of Budesonide +Formoterol Inhaler vide S.O. 156(E) dated 27.04.2016 wherein, unit is mentioned as each metered dose. Metered dose is referred to as two formulations based on MDI (Metered Dose Inhalation).	NPPA has notified the ceiling price for Budesonide+Formoterol & Tiotropium based formulation in MDI/DPI dose. As NLEM, 2015 does not differentiate between MDI and DPI dose. Further, committee of experts in its meeting dated 02.05.2017 observed that Budesonide is a respiratory medicine, the conventional dosage is 100 mcg, 200 mcg and 400 mcg. This is often given in combination with Formoterol in doses of 6 mcg. There are different delivery systems available for inhalations ranging from simple/conventional inhalation device to Metered dose inhalator/ Digital inhaler and Autohaler. There

	<p>The worksheet for the prices notified on 27.04.2016 confirms that working has been done based on MDI formulations similarly, for Tiotropium based formulation, NPPA has notified ceiling price vide S.O. 1687(E) dated 09.05.2016. However, vide S.O. 1039(E) dated 01.04.2017, the unit has been changed, MDI has been substituted with MDI/DPI and the unit has been indicated as 1 dose.</p> <p>Company has pointed out that MDI and DPI, both the formulations are completely different. MDI means Metered Dose Inhalation, which comes in Aerosol form. DPI means Dry Powder Inhalation, which comes in the form of capsules. Aerosol is actuated directly in the patient's mouth for inhalation. However, in case of DPI, the capsules are broken in a special device, and the patient inhales the dry powder from the device by placing the same in mouth. Further, the method of administration is decided by the doctors depending on the patient's medical requirement. The manufacturing license is also different for both dosages. The process of manufacturing is also different.</p>	<p>may be other different variants/drug dispensing mechanisms available in the market. Although, they offer technical advantage/ease of administration say in old age, children or patients with poor coordination ability, there is no significant clinical efficacy and therapeutic outcome once an adequate dose is administered/delivered. Hence, separate price for metered dose counter/digital inhaler and autohaler may not be considered, rather they should be clubbed together for the purpose of price fixation.</p> <p>“The committee observed that the inhalation drugs used for bronchial asthma are given by different methods like MDI, DPI, soft-mist inhaler and nebulizer. The DPI can be given as a single dose, multi dose, and powder assisted system. This has advantage of portability, does not require much coordination and no spacer is required whereas MDI requires aerosol which is also portable and independent reproducing dosage and has relatively low cost. Thus, there is not much significant clinical advantage in terms of therapeutic outcome by using DPI over MDI”.</p>
2.	<p>The company also submitted the presentation to NPPA to rectify the error in notification and the same was not rectified by NPPA so far.</p>	<p>The ceiling prices were notified for these formulations on 28.4.2016 and NPPA has applied only WPI effect on 01.04.2017 and GST effect on 30.06.2017. The 30 days has already been elapsed. The same price was applied on DPI also. The matter is subjudice M/s. Zydus healthcare limited, M/s. Cipla limited, M/s. Macleods limited and M/s. Glenmark limited have challenged the clubbing of MDI and DPI in the Delhi High Court and next hearing will be in the month of February, 2018.</p>

3.	Company has pointed out that they have only implemented the prices notified for their MDI range of formulation as inclusion of DPI formulations are not in line with the provisions of DPCO, 2013.	Company has been violating the provisions of DPCO, 2013 as they have not implemented the ceiling price for DPI range of formulations.
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4. During the personal hearing, the company representatives stated that NPPA had fixed price in 2016 only for MDI, which was implemented by the company. However, subsequently in April, 2017, NPPA announced price revision for giving effect to WPI and without reworking the price as per para 4 of DPCO, 2013, incorporated DPI as well. Since, the price was for MDI only, the company implemented the said price for MDI formulations. The company representative further stated that had the NPPA reworked the price incorporating DPI prices as well, the company would have implemented the same as well.

5. **Examination:**

5.1 The issue of considering separate price fixation for metered dose counter/digital inhaler and autohaler was discussed in the Expert Committee of NPPA on 8.5.2017. The Expert Committee of NPPA decided that separate price for metered dose counter/digital inhaler and autohaler may not be considered, and should be clubbed together for the purpose of price fixation, on the ground that there is no significant difference in clinical efficacy and therapeutic outcome once an adequate dose is administered/ delivered.

5.2 In view of the above, NPPA needs to re-fix the ceiling prices of Budesonide (A) + Formoterol (B) [Inhalation (MDI/DPI) 400 MCG(A)+6MCG(B); 200MCG(A)+6MCG(B) and 100MCG(A)+6MCG(B)] and Tiotropium Inhalation (DPI) 18Mcg/Dose by considering PTR of both types of inhalers, i.e. Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI).

6. **Decision:**

“NPPA is hereby directed to re-fix the ceiling prices of Budesonide (A) + Formoterol (B) [Inhalation (MDI/DPI) 400 MCG(A)+6MCG(B); 200MCG(A)+6MCG(B) and 100MCG(A)+6MCG(B)] and Tiotropium Inhalation (DPI) 18Mcg/Dose by considering PTR of both types of inhalers, i.e. Metered Dose Inhaler (MDI) and Dry Powder Inhaler (DPI). ”

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 Lupin Limited, C/4, Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mumbai-400 051.
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