

No. 31015/27/2016-PI.I
GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS & FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

B Wing, Janpath Bhavan,
New Delhi 110 001

Subject: Review application of M/s Cipla Ltd. against price fixation of “Budesonide Inhalation 100 mcg & 200 mcg etc.” vide NPPA order No. S.O. 1561(E) dated 29/03/2016 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).

Ref: 1) Review application dated 14.05.2016
2) NPPA notification under review S.O. No.1561(E) dated 27.04.2016
3) Record Note of discussions held in the personal hearing held in the matter on 22.6.2016.

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s Cipla Ltd. (hereinafter called the petitioner) against notification S.O. No.1561(E) dated 27.04.2016 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of Budesonide Inhalation 100 mcg & 200 mcg etc.

2. The petitioner has contended as under:

NPPA has issued an erroneous notification because –

- (i) NPPA has failed to recognize that their products have a different packaging and helps dosage compliance and hence it should have a different price fixed for itself;
- (ii) In case of their product “Formoterol 6 mcg + Budesonide 200 mcg inhaler per dose – (AUTOHALER) – Breath Actuated Device, the calculation by NPPA is erroneous because the data provided in the working sheet is wrong.

The company submitted that their products fall under the provisions of 11(3) and hence the same should be treated differently by way of fixing pricing specifically for this.

The company requested that following corrections should be made :-

	Current CP per dose &SO No. 1561(E) dated 27 th April '16	Ceiling Price to be revised to
Budesonide 100 Inhaler per dose with Dose Counter	Rs.1.22	Rs.1.23
Budesonide 200 Inhaler per dose with Dose Counter	Rs.1.50	Rs.1.56
Formoterol 6mcg + Budesonide 100mcg Inhaler per dose with Dose Counter	Rs.1.74	Rs.1.84
Formoterol 6mcg + Budesonide 200mcg Inhaler per dose with Dose Counter	Rs.2.19	Rs.2.32

Formoterol 6mcg + Budesonide 400mcg Inhaler per dose wth Dose Counter	Rs.2.74	Rs.2.85
Formoterol 6mcg + Budesonide 200mcg Inhaler per dose (AUTOHALER) – Breath Actuated Device	Rs.2.19	Rs.3.72

3. NPPA representative stated that the ceiling price Rs.1.22 & Rs.1.50 per dose for Budesonide Inhalation 100 mcg. and 200 mcg, Rs.1.74, Rs.2.19 and Rs.2.74 per dose for Budesonide + Formoterol inhalation (100 mcg + 6 mcg, 200 mcg + 6 mcg, 400 mcg + 6 mcg) per dose is fixed vide SO 1561(E) based on data submitted by Pharma Trac. Company is directed to approach NPPA in line with OM F.No.19(714)/2016/Div.-II/DP/NPPA, dated 20th May, 2016 with regard to their PTR. Company is also advised to approach NPPA with required documents / information so that their case may be examined by NPPA under para 11(3) of DPCO, 2013.

4. In the personal hearing, the company representative has stated as under:-

- (i) Their products Budecort 100 (covered under section 28 of NLEM), Budecort 200 (covered under Section 28 of NLEM), Foracort 100, Foracort 200 and Foracort 400 (covered under section 28 of NLEM) are fitted with a unique dose counter that lets the patient know the remaining doses left in the canister. This is a unique device, **the patent for which is pending. This product because of the dose counter falls is covered under section 11 (3) of DPCO 2013 and therefore would require a separate price to be notified by the NPPA.** On the contrary, the NPPA vide its notification no. 1561 (E) dated 27th April 2016, has fixed a price which is an average of all Brands in the market with and without dose counter.
- (ii) Their product Foracort 200 Autohaler (Formoterol 6mcg + Budesonide 200mcg) is also available with a breath actuated device. In a conventional inhalation, a patient has to synchronise breathing with the actuation of the inhaler whereas in the case of Foracort 200 Autohaler, the device automatically releases a dose as soon as the patient inhales. This device is extremely innovative and useful for the patients and is also expensive. This product too should be treated separately as per the provisions of Para 11 (3).

In view of the discussion held on 22.06.2016, the petition company has submitted the relevant data, copies of invoices to retailers/MAT data/Samples of Budecort 100 mcg/200 mcg inhalation with dose counter, Foracort 100/200/400 inhaler with dose counter and Foracort 200 Autohaler, to the NPPA vide its letter dated 11.7.2016, with a copy to this Department.

5. Attention is invited to this Department's Order No.S.O. 1192(E), dated 22.03.2016 published in the Gazette of India 'Extraordinary', which inter alia provides as under:-

In the Drugs (Prices Control) Order, 2013 in Paragraph-11, after sub-paragraph (2), the following sub-paragraphs shall be inserted, namely :-

“(3) Notwithstanding anything contained in sub-paragraphs (1) and (2), in the case of injections or inhalation or any other medicine for which dosage form or strength or both are not specified in the Schedule-I of the Drugs (Prices Control) Order, 2013, the Government may fix and notify separate ceiling price or retail price for such formulations with specific therapeutic rationale, considering the type of packaging or pack size or dosage compliance or content in the pack namely liquid, gaseous or any other form, in the unit dosage as the case may be, conforming to Indian Pharmacopeia or other standards as specified in the Drugs and Cosmetics Act, 1940 (23 of 1940) and the rules made thereunder for the same formulation.

(4) The Government shall form a Committee of Experts, as it may deem fit, within a period of fifteen days from the date of issue of this order, to recommend fixing of separate ceiling price of scheduled formulations or retail price of a new drug as per the above parameters.”

4. **Decision of the Government:**

NPPA shall examine this case in accordance with para 11(3) & (4) of DPCO, 2013. The petitioner may bring any relevant data, copies of invoices to retailers/MAT data/Samples of Budecort 100/200 inhaler with dose counter, Foracort 100/200/400 inhaler with Dose Counter and Foracort 200 Autohaler, before the Expert Committee. The recommendations of Expert Committee may be examined by NPPA on merit and the ceiling price of aforesaid formulation be fixed afresh in the light thereof.

The review petition of the company is hereby disposed off accordingly.

Issued on this date, the 14th day of September, 2016.

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

To

1. **M/s. Cipla Ltd.**
Cipla House, Peninsula Business Park,
Ganpatrao Kadam Marg,
Lower Parel,
Mumbai-400 013.

**2. The Member Secretary,
National Pharmaceutical Pricing Authority,
YMCA Cultural Centre Building, New Delhi-110001**

Copy to :

- 1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.**
- 2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
- 3. T.D., NIC for uploading the order on Department's Website**