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* **IN THE HIGH COURT OF DELHI AT NEW DELHI**

\# **CNR No. DLHC010520152026**

\+ **W.P.(C) 15965/2026 & CM APPL. 74801/2026, CM APPL. 74802/2026, CM APPL. 74803/2026**

ASTRAZENECA PHARMA INDIA LIMITED THROUGH ITS AUTHORIZED REPRESENTATIVE .....Petitioner

Through: Mr. Amit Sibal, Sr. Adv. with Ms. Krishna Sarma, Ms. Archita Phookun, Mr. Navnit Kumar, & Mr. Shubhankar Gupta, Advs.

versus

NATIONAL PHARMACEUTICAL PRICING AUTHORITY THROUGH ITS CHAIRMAN MEMBER SECRETARY & ANR. .....Respondents

Through: Ms. Saumya Tandon, CGSC with Mr. Gaurav Singh Sengur, Adv. for respondents.

CORAM:
HON'BLE MR. JUSTICE AMIT MAHAJAN

O R D E R

% 29.10.2026

1. Petitioner is aggrieved by the impugned demand notice dated 05.10.2026, issued by the National Pharmaceutical Pricing Authority, thereby asking the petitioner to deposit a sum of ₹151,19,66,035/- comprising of overcharged amount of ₹86,99,14,796/- and the interest of ₹64,20,51,239/-.

2. It is alleged that the petitioner is selling its product at a price higher than the price fixed for such formulation.

3. Learned Sr. Counsel for the petitioner submits that it is not in dispute that doses of the petitioner product is different than the dose as

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covered in the Schedule of the Drugs (Price Control) Order, 2013. He submits that the drugs with specific strength and doses which found reference in NELM 2011 and the petitioner's product having different doses form and strength cannot be equated. He submits that the approval, to the petitioner, to import the product with the specific doses, was granted way back in the year 2003 and the petitioner has been selling the said product since the said the year without any objection.

4. He submits that even otherwise the ceiling price of a product, which the respondents claim to be similar to the petitioner's products, was fixed in the year 2019, whereas the demand has been raised from the year 2016 onwards.

5. He submits that, in somewhat similar circumstances, a Coordinate Bench of this Court in W.P.(C) 3912/2018 had categorically held that the ceiling prices can be fixed only on the formulations having the specific doses and forms and NPPA does not have any power in respect of formulation in other doses and forms which are given specific permission by the respondent authorities for being marketed.

6. Learned Senior Counsel for the petitioner has taken this Court through the Import Licence granted to the petitioner mentioning the doses and strength of the drug in the following manner:

> *"File No: 4-32/01-DC*
> *FORM 45*
> *(See rules 122A, 122D and 122DA)*
> **********
> *Number of the permission and date of issue M.P.(642)-Import*
>
> *Sub: Astrazeneca Pharma India Ltd.*
> *Crescent Towers, 32/1-2, Crescent Road, Plot No. 5039, Bangalore-1.*

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Hereby permitted to import the following new drug formulation under rule 122 A / 122 D of the Drugs and Cosmetics Rules, 1945.

(1)	*Name of the Drug*	*Fixed dose combination of Budesonide Blue Formoterol inhalation powder.*
(2)	*Dosage form*	*"Inhalation Powder"*
(3)	*Composition*	*Each inhalation (1dose) contains – Budesonide 80 mcg/160 mcg and Formoterol (as fumatate dihydrate) 4.5 mcg.*
(4)	*Indications*	*Treatment of Asthama where the use of corticosteroid and long acting beta agnostic combination appropriate.*

Date: 6 JUNE 2003

Signature_____
Sd/-
Ashwini Kumar
Drugs Controller General (India)
(Name and designation of Licensing Authority)"

7. Attention of this Court has also been drawn to the doses and strength of the drug which has been mentioned in Section 24.1.2 of Schedule I of the Drugs (Price Control), Order, 2013 and the same reads as under:

	Medicine	*Level of Healthcare*	*Dosage form(s) and strength(s)*
24.1.2	*Budesonide (A) + Formoterol (B)*	*P, S, T*	*Inhalation (MDI/DPI) 100 mcg (A) + 6 mcg (B)* *Inhalation (MDI/DPI) 200 mcg (A) + 6 mcg (B)* *Inhalation (MDI/DPI) 400 mcg (A) + 6 mcg (B)*

8. It is further submitted that the National Pharmaceutical Pricing Policy, 2012 in paragraph 4(iii) specifically provides that span of price control shall be as per the doses and strength as listed in NLEM 2011.

9. Issue notice.

10. Ms. Saumya Tandon, CGSC accepts notice on behalf of

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respondents.

11. In view of the submissions recorded as above, the petitioner has made out a *prima facie* case that its product may not fall within the category of drug whose price has been controlled under the Drugs (Price Control), Order, 2013.

12. Reply, if any, be filed before the next date of hearing.

13. The respondents are directed not to take any coercive steps till the next date of hearing.

14. List on 11.01.2027.

AMIT MAHAJAN, J

OCTOBER 29, 2026
"SK"

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