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 Government of India  
 Ministry of Chemicals and Fertilizers  
 Department of Pharmaceuticals  
 National Pharmaceutical Pricing Authority

New Delhi, 26 February, 2019

**ORDER**

**S.O. 1028(E)** In implementation of directions given in line with review orders issued by the Department of Pharmaceuticals (DOP) vide order(s) specified in column (6) of the table herein below passed by the Department of Pharmaceuticals under para 31 of Drugs (Prices Control) Order, 2013 and in exercise of the powers conferred by paragraphs 4, 6, 10, 11, 14, 16, 17 and 18 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013 and S.O. 701(E) dated 10th March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers, and in supersession of the Order(s) of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) specified in the Column (7) of the table regarding formulation specified as mentioned in the table in so far as it relates to formulation pack mentioned in the table below, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby fixes/revises the price as specified in column (5) of the table herein below as ceiling price exclusive of goods and services tax applicable, if any, in respect of the Scheduled formulation(s) specified in the corresponding entry in column (2) of the said Table with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof:

**TABLE**

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)	Review Order number and date	Existing SO number and date
(1)	(2)	(3)	(4)	(5)	(6)	(7)
1.	Budesonide	Inhalation (MDI) 100 mcg / dose	Per Metered Dose	1.19	i. 31015/27/2016-PI.I dated 14.09.2016 ii. 31015/52/2017-Pricing dated 30.10.2017 iii. 31015/54/2017-Pricing dated 26.06.2018	1461(E) dated 02.04.2018 (at Sl. No. 112)
2.	Budesonide	Inhalation (MDI) 200 mcg / dose	Per Metered Dose	1.48		1461(E) dated 02.04.2018 (at Sl. No. 113)
3.	Budesonide (A)+ Formoterol (B)	Inhalation (MDI) 100 mcg (A) + 6 mcg (B)	Per Metered Dose	1.77		1461(E) dated 02.04.2018 (at Sl. No. 118)
4.	Budesonide (A)+ Formoterol (B)	Inhalation (MDI) 200 mcg (A) + 6 mcg (B)	Per Metered Dose	2.51		1461(E) dated 02.04.2018 (at Sl. No. 119)
5.	Budesonide (A)+ Formoterol (B)	Inhalation (MDI) 400 mcg (A) + 6 mcg (B)	Per Metered Dose	2.86		1461(E) dated 02.04.2018 (at Sl. No. 120)
6.	Budesonide	Inhalation (DPI) 100 mcg/dose	Per Dose	1.87		1461(E) dated 02.04.2018 (at Sl. No. 112)

7.	Budesonide	Inhalation (DPI) 200 mcg/dose	Per Dose	2.71		1461(E) dated 02.04.2018 (at Sl. No. 113)
8.	Budesonide (A)+ Formoterol (B)	Inhalation (DPI) 100 mcg (A) + 6 mcg (B)	Per Dose	3.56		1461(E) dated 02.04.2018 (at Sl. No. 118)
9.	Budesonide (A)+ Formoterol (B)	Inhalation (DPI) 200 mcg (A) + 6 mcg (B)	Per Dose	4.73		1461(E) dated 02.04.2018 (at Sl. No. 119)
10.	Budesonide (A)+ Formoterol (B)	Inhalation (DPI) 400 mcg (A) + 6 mcg (B)	Per Dose	6.04		1461(E) dated 02.04.2018 (at Sl. No. 120)
11.	Tiotropium	Inhalation (MDI) 9 mcg/dose	Per Metered Dose	2.08		1461(E) dated 02.04.2018 (at Sl. No. 799)
12.	Tiotropium	Inhalation (DPI) 18 mcg/dose	Per Dose	8.72		1461(E) dated 02.04.2018 (at Sl. No. 798)
13.	Dexamethasone	Injection 4mg/ml	Per 2ML Pack	8.75	i. 31015/15/2017- Pricing dated 10.01.2019 ii. 31015/16/2017- Pricing dated 10.01.2019	1461(E) dated 02.04.2018 (at Sl. No. 243)
14.	Gentamicin	Injection 40mg/ml	Per 2ML Pack	7.89	31015/21/2017- Pricing dated 10.01.2019	1461(E) dated 02.04.2018 (at Sl. No. 353)

**Note:**

- (a) All manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.
- (b) All the existing manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any, shall continue to maintain the existing MRP in accordance with paragraph 13 (2) of the DPCO, 2013.
- (c) The manufacturers may add goods and services tax only if they have paid actually or if it is payable to the Government on the ceiling price mentioned in column (5) of the above said table.
- (d) The ceiling price for a pack of the scheduled formulation shall be arrived at by the concerned manufacturer in accordance with the ceiling price specified in column (5) of the above table as per provisions contained in paragraph 11 of the Drugs (Prices Control) Order, 2013. The manufacturer shall issue a price list in Form-V from date of Notification as per paragraph 24 of the DPCO, 2013 to NPPA through IPDMS and submit a copy to State Drug Controller and dealers.
- (e) As per para 24(4) of DPCO 2013, every retailer and dealer shall display price list and the supplementary price list, if any, as furnished by the manufacturer, on a conspicuous part of the premises where he carries on business in a manner so as to be easily accessible to any person wishing to consult the same.
- (f) Where an existing manufacturer of scheduled formulation with dosage or strength or both as specified in the above table launches a new drug as per paragraph 2 (u) of the DPCO, 2013 such existing

manufacturer shall apply for prior price approval of such new drug to the NPPA in Form I as specified under Schedule-II of the DPCO, 2013.

- (g) The manufacturers of above said scheduled formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of scheduled formulations in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of production and / or import of scheduled formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.
- (h) The manufacturers not complying with the ceiling price and notes specified hereinabove shall be liable to deposit the overcharged amount along with interest thereon under the provisions of the Drugs (Prices Control) Order, 2013 read with Essential Commodities Act, 1955.
- (i) Consequent to the issue of ceiling prices of such formulations as specified in column (2) of the above table in this notification, the price order(s) fixing ceiling or retail price, if any, issued prior to the above said date of notification, stand(s) superseded.

(Prasenjit Das)  
Assistant Director