(Published in Part II, Section 3, Sub-section (ii) of the Gazette of India, Extraordinary) Government of India Ministry of Chemicals and Fertilizers Department of Pharmaceuticals National Pharmaceutical Pricing Authority

New Delhi, the 06<sup>th</sup> January, 2023

## ORDER

S. O. 88(E):- 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 30<sup>th</sup> May, 2013 and S.O. 5249(E) dated 11<sup>th</sup> November, 2022 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the prices 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 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:

SI. No.	Name of the Scheduled Formulation	Dosage form and strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1.	Buprenorphine (A)	Tablet (Sub-lingual)		
	+Naloxone (B)	2mg(A)+0.5mg(B)	1 Tablet	32.98
2.	Buprenorphine (A)	Tablet (Sub-lingual)		
	+Naloxone (B)	0.4mg(A)+0.1mg(B)	1 Tablet	10.54
3.	Buprenorphine	Tablet (Sub-lingual)0.4mg	1 Tablet	8.41
	Tenofovir			
	Alafenamide			
4.	Fumarate (TAF)	Tablet 25mg	1 Tablet	43.59

## TABLE

## Note:

- (a) All manufacturers of scheduled formulation, 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 price of such formulation 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.

PN/238/106/2022/F F. No. 8(106)/2022/D.P./NPPA-Div.-II

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