## (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 18th December, 2019

## **ORDER**

S. O. 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 5, 11 and 15 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, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), hereby fixes, the price as specified in column (5) of the table herein below as the retail price, exclusive of goods and services tax, if any, in relation to the formulation specified in the corresponding entry in column (2) of the said Table with the strength, unit and name of manufacturer & marketing company, as specified in the corresponding entries in columns (3), (4) and (8) thereof;

## **Table**

Sl. No.	Name of the Formulation	Dosage form & Strength	Unit	Retail Price (Rs.)	Review Order number and date	Existing SO number &	Manufacturer & Marketing Company
						date	respectively
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
1.	Emtricitabine +	Each film coated tablet	1	32.49	31015/10/2019-	4062(E) dated	M/s Hetero Labs Ltd. /
	Tenofovir tablet	contains:	Tablet		Pricing dated	08.11.2019	M/s Emcure
		Emtricitabine IP 200 mg			30.08.2019	(at Sl. No. 4)	Pharmaceuticals Ltd.
		Tenofovir Alafenamide				,	
		Hemifumarate eq to Tenofovir					
		Alafenamide 10 mg					

Note:

- (a) The manufacturer of above mentioned formulations i.e. "new drug" under paragraph 2(u) of the DPCO, 2013 shall fix the retail price as specified in column (5) of the table hereinabove.
- (b) The manufacturer may add goods and services tax only if they have paid actually or it is payable to the Government on the retail price mentioned in column (5) of the above said table.
- (c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (5) of the above table as per provisions contained in paragraph 11 of the DPCO, 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.
- (d) 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.
- (e) The above mentioned retail prices are applicable only to the manufacturer / marketer as mentioned above for generic / any brand of the same composition / strength of the subject formulations, subject to fulfillment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/ rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturers/marketing companies.
- (f) In case the retail price of any of the aforesaid formulations is not complied with, as per instant price notification and notes specified hereinabove, then the concerned manufacturer/marketing company shall be liable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.

PN/203/71/2019/F

F. No. 8(71)/2019/D.P./NPPA-Div.-II