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

New Delhi, 8th June, 2023

ORDER

S.O. 2542(E)- Whereas the National Pharmaceutical Pricing Authority (NPPA) was established vide Resolution No. 33/7/97-PI.I dated 29th August 1997 of the Government of India in the Ministry of Chemicals and Fertilizers to fix/revise, monitor prices of drugs/formulations and oversee the implementation of the Drugs (Prices Control) Order (hereinafter referred as DPCO); and whereas the Government of India by S.O. 1349(E) dated 30th May 2013 in exercise of the powers conferred by Section 3 and 5 of the Essential Commodities Act, 1955 (10 of 1955) has delegated the powers in respect of paragraphs 4,5,6,7,8,9,10,11,12,13,14,15,16,18,19, 20,21,23,24,25,26,27,28,29,30 and 32 of the DPCO, 2013 to the NPPA to exercise the functions of the Central Government;

2. And whereas the aim of the DPCO, 2013 issued under section 3 of Essential Commodities Act, 1955, is to ensure that essential drugs are available to all at affordable prices.

3. Whereas, the Department of Pharmaceuticals (hereinafter referred as DOP) has amended Schedule I of the DPCO 2013 vide S.O. 5249(E) dated 11.11.2022 based on National List of Essential Medicine (hereinafter referred as NLEM 2022).

4. Whereas under the revised Schedule I, certain new formulations have been added. In respect of some of these formulations, high Inter brand variation within the same company has been observed. The matter was deliberated in 111th Authority meeting and based on reasons detailed in S. O. 1579(E) dated 31.03.2023, the ceiling prices of such formulations have been fixed under Para 19 of DPCO 2013 and notified vide the said notification. Similar inter brand price variation has been observed in case of the scheduled formulation "Latanoprost Drops 0.005%". The matter has been deliberated in 113th Authority meeting and based on reasons as detailed in S.O. 1579(E) dated 31.03.2023, the Authority has approved the ceiling price of the said formulation under Para 19 of DPCO 2013.

5. Therefore, in exercise of the powers conferred by paragraphs 19 of the DPCO, 2013, read with S.O. 1394(E) dated the 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, the NPPA hereby fixes the ceiling prices exclusive of goods and services tax applicable, if any, as specified in column (5) of the table in respect of the Scheduled formulations 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 and strength	Unit	Ceiling Price fixed under NLEM, 2022 (Rs.)
(1)	(2)	(3)	(4)	(5)
1	Latanoprost	Drops 0.005%	1 ML	232.57

Notes:

- (a) All manufacturers of Latanoprost Drops 0.005%, selling the branded or generic or both the versions of Latanoprost Drops 0.005%, 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 the said scheduled formulation 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 formulation having MRP lower than the ceiling price specified in column (5) in the above table plus GST 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) Information about the revision, if carried out, shall be forwarded to the Government in either electronic or physical form in Form-II within a period of fifteen days of such revision and non-submission of information under this sub-paragraph shall be construed as non-revision of maximum retail price (MRP) and the concerned manufacturer shall be liable to deposit the amount charged over and above the pre-revised maximum retail price (MRP), alongwith interest thereon from the date of overcharging.
- (e) 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.
- (f) 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.

- (g) 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(1)(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.
- (h) 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.
- (i) 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.
- (j) 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/245/113/2023/F

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