(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

ORDER

New Delhi, the 2nd February, 2023

S.O. 487(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 30th May, 2013 and S.O. 5249(E) dated 11th November, 2022 issued by the Government of India the Ministry of Chemicals and Fertilizers and in supersession of the Order of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No SO 1505(E) dated 30th March, 2022 in so far as it relates to formulation packs mentioned in the table A below, manufactured by the manufacturers specified in Table B for specified products and pack-sizes, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the price as specified in column (5) of the table A 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 A with the dosage form & strength and unit specified respectively in the corresponding entries in columns (3) and (4) thereof for manufacturers specified in Table B.

Table A

Sl. No	Medicines	Dosage form and Strength	Unit	Ceiling price
(1)	(2)	(3)	(4)	(5)
1	Mannitol	Injection 20% in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features	Per ml	0.36

TABLE 'B'

Sl. No.	Name of Manufacturer
(1)	(2)
1	M/s Otsuka Pharmaceutical India Private Ltd.
2	M/s Denis Chem Lab Ltd.
3	M/s Rusoma Laboratories Pvt. Ltd.

(a) The manufacturers of scheduled formulations, selling abovesaid products / brand name of scheduled formulations at 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) 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) Any other manufacturer claiming separate ceiling price for Mannitol Injection 20% in 100 ml pack for packages in non-glass container in plastic bottle with euro head having special features shall apply to NPPA for separate ceiling price approval.

(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 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.

PN/240/108/2023/F F. No. 8(108)/2023/D.P./NPPA-Div.-II

(Mahaveer Saini)
Deputy Director (Pricing)