(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 31stMarch, 2023

S.O. 1575(E)- In exercise of powers, conferred by sub paragraph (3) and (4) of paragraph 11, 14 and 16 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013, S.O. 5249(E) dated 11th November, 2022 issued by the Government of India in 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) S.O. No. 487(E) dated 02.02.2023 read with corrigendum,in so far as it relate 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, hereby revises the price based on Wholesale price index(WPI) of 2022 as specified in column (5) of the Table A herein below as separate ceiling price exclusive of Goods and Services Tax applicable, if any, in respect of the scheduled formulations specified in the corresponding entry in column (2) of the said Table with the dosage form and strength and unit/packaging specified respectively in the corresponding entries in columns (3) and (4) thereof:

Table A

Price Revision as per Annual Wholesale Price Index (WPI) @ 12.1218% increase.

SI No	Medicines	Dosage form and Strength	Unit	Ceiling price (wef01.04.2023 with WPI @ 12.1218%)
(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	0.40

TABLE 'B'

SI. 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.
4	M/s Sachin Parenteral Pvt. Ltd.

- (a) The ceiling prices are applicable with effect from 01.04.2023 (ceiling prices are inclusive of Wholesale Price Index (WPI) @12.1218% for the year 2022 over 2021).
- (b) The manufacturers of scheduled formulations, selling abovesaid products/brandnameof 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.
- (c) The manufacturers of above mentioned scheduled formulations having MRP lower than the ceiling price notified vide S.O. No. 487(E) dated 02.02.2023 read with corrigendum(plus Goods and Services Tax as applicable, if any), may revise the existing M.R.P. of their formulations, on the basis of WPI @ 12.1218% for year 2022over 2021in accordance with paragraph 16(2) of DPCO, 2013.

- (d) 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.
- (e) 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.
- (f) 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 nonsubmission 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.
- (g) 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
- (h) 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.
- (i) 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.
- (j) 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.
- (k) 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.

PN/243/111/2023/F

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