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

New Delhi, the 15th May, 2017

ORDER

S.O.1569(E) In implementation of directions given in line with review orders issued by the Department of Pharmaceuticals (DOP) vide letters no. 31015/71/2016-PI.I dated 30.01.2017 (Phenobarbitone 30mg Tablet & Sodium Valproate 200mg Tablet); no. 31015/100/2016-PI.I dated 10.03.2017 (Pheniramine 22.75mg/ml Injection) & no. 31015/94/2016-PI.I dated 05.4.2017 (Adrenaline 1mg/ml Injection) respectively passed by the Department of Pharmaceuticals under para 31 of Drugs (Prices Control) Order, 2013 and in exercise of the powers conferred by paragraphs 4, 10, 11, 14, 16, 17 and 18 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 of the Government of India in the Ministry of Chemicals and Fertilizers (National Pharmaceutical Pricing Authority) No. S.O. 2195(E), dated 23rd June, 2016 at (Sl. No. 8 & 9) & S.O. 1039(E) dated 1st April, 2017 at (Sl. No. 502 & 590) (Phenobarbitone 30mg Tablet & Sodium Valproate 200mg Tablet); No. S.O. 3431(E), dated 10th November, 2016 at (Sl. No. 1) & S.O. 1039(E) dated 1st April, 2017 at (Sl. No. 498) (Pheniramine 22.75mg/ml Injection) & No. S.O. 3181(E), dated 7th October, 2016 at (Sl. No. 10) & S.O. 1039(E) dated 1st April, 2017 at (Sl. No. 18) (Adrenaline 1mg/ml Injection) respectively regarding formulation packs mentioned in the table in so far as it relates to formulation packs mentioned in the table below, except in respect of things done or omitted to be done before such supersession, the National Pharmaceutical Pricing Authority, hereby fixes the price as specified in column (5) of the table herein below as ceiling price exclusive of local 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:

TABLE

Sl. No.	Name of the Scheduled Formulation	Dosage form & Strength	Unit	Ceiling Price (Rs.)
(1)	(2)	(3)	(4)	(5)
1.	Phenobarbitone	Tablet 30mg	1 Tablet	1.16
2.	Sodium Valproate	Tablet 200mg	1 Tablet	2.93
3.	Pheniramine	Injection 22.75 mg/ml (2 ML Pack)	1 ML	1.44
4.	Pheniramine	Injection 22.75 mg/ml (10 ML Pack)	1 ML	1.06
5.	Adrenaline	Injection 1mg/ml	1 ML	14.81

Note:

(a) All manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus local taxes 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 local taxes 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 local taxes 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 local taxes 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) The formulation of Sodium Valproate includes combination of Sodium Valproate and Valproic Acid both together corresponding to Sodium Valproate of the stated strength.

(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/177/45/2017/F F. No. 8(45)/2017/D.P./NPPA-Div.-II

(BALJIT SINGH)
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