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

New Delhi, the 23rd November, 2017

ORDER

S.O. 3724(E) Whereas, the Department of Pharmaceuticals (hereinafter referred as DOP) has amended Schedule I of the Drugs Price Control Order (hereinafter referred as DPCO) 2013 vide S.O. 701(E) dated 10.03.2016 based on revised National List of Essential Medicine (hereinafter referred as NLEM) 2015;

and

02. Whereas on amendment of the list of scheduled formulations, paragraph 17 of the DPCO 2013 requires fixation of the ceiling prices of formulations (i.e. medicines) added in the Schedule I to be fixed as per the provisions of the DPCO, 2013 within a period of sixty days from the date of amendment;

and

03. Whereas the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) initiated the process of the ceiling price fixation in March 2016. In this connection, NPPA vide Office Memorandum (i.e. OM) 19(697)/2016/Div II/NPPA dated 4.4.2016 had uploaded a list of the scheduled formulations for which reference market based data required for price fixation was not available. The said list was subsequently amended and displayed again vide OMs dated 28.4.2016, 13.5.2016, 10.1.2017 and 8.7.2017. Copies of the aforesaid OMs were also sent to Drugs Manufacturers Associations requesting for submission of market based data and whereas NPPA had also suggested the Department of Pharmaceuticals to amend DPCO 2013 so as to facilitate consideration of the State Institutional Procurement Price for such scheduled formulations where market based data are not available to facilitate ceiling price fixation;

and

04. Whereas on the basis of inputs from the manufacturer and official data collection agency viz AIOCD AWACS in respect of certain scheduled formulations where market based prices could be traced, NPPA has fixed the ceiling prices of such scheduled formulations. NPPA has so far fixed the ceiling prices of 821 formulations on the basis of available data. However, even after a number of attempts made to obtain the relevant and reliable market based data, NPPA has not been able to fix the ceiling prices of remaining scheduled formulation for the want of requisite market data;

and

05. Whereas, it is obligatory on the part of the NPPA to revise the ceiling prices of all the drugs notified under the Schedule I of DPCO, 2013 so as to ensure the benefit of fair and reasonable ceiling prices to the consumers of such essential medicines falling in therapeutic category of cardiovascular, blood products and plasma substitutes etc. to protect public interest, there is a necessity to adopt alternative methods of price fixation;

and

06. Whereas NPPA also sought information from the various Government Procurement Agencies under Central Government and States and State Medical Services Corporation, as it is necessary to fix ceiling prices of scheduled formulations. Accordingly, in the absence of the relevant market based data in the Pharmatrac report of AIOCD- AWACS, it has been decided in the Authority Meeting held in the NPPA on 19/9/2017 to fix the ceiling prices of remaining scheduled formulations on the basis of procurement prices;

and

07. Now, in exercise of the powers conferred by paragraphs 19 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, which has been upheld by the Honourable High Court and also Hon'ble Supreme court of India, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA) hereby fixes the prices as specified in column (5) of the table herein below as 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 & 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.	Morphine	SR Tablet 30 mg	1 Tablet	4.94
2.	Alteplase	Powder for Injection 20 mg	Each Pack	17235.00
3.	Alteplase	Powder for Injection 50 mg	Each Pack	35985.00
4.	Gadobenate	Injection 529 mg/ml	1 ML	98.90
5.	Haemodialysis fluid	As license	1 ML	0.03695
6.	Furosemide	Oral liquid 10 mg/ml	1 ML	0.29
7.	Glucose	Injection 50%	1 ml	0.44

Note:

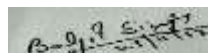
- (a) All manufacturers of scheduled formulations, selling the branded or generic or both the versions of scheduled formulations at a price higher than the ceiling price (plus goods and services tax as applicable) so fixed and notified by the Government, shall revise the prices of all such formulations

downward not exceeding the ceiling price specified in column (5) in the above table plus goods and services tax as applicable, if any.

- (b) 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 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) 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) 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.

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F. No. 8(50)/2017/D.P./NPPA-Div.-II



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