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

New Delhi, the 3rd March, 2020

ORDER

S. O. (E) – In implementation of directions given in line with review orders issued vide orders no. 31015/76/2017-Pricing dated 21.03.2018, 31015/81/2017-Pricing dated 21.03.2018, 31015/84/2017-Pricing dated 21.03.2018, 31015/82/2017-Pricing dated 21.03.2018 and 31015/79/2017-Pricing dated 21.03.2018, the matter was placed before the Multidisciplinary Committee of Experts for examination under para 11(3&4) of DPCO 2013.

And whereas the Multidisciplinary Committee of Experts examined and noted that the ringer lactate injection in packages having special features have a minor innovation in the packaging like (i) self collapsibility and self-sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture / infusion/admixing levels, which may hereinafter referred to as pack having special features.

And whereas, the Multidisciplinary Committee of Experts recommended that an increase of 15% over and above the ceiling price notified for ringer lactate injection may be allowed to the products of the companies for which the review orders have been issued by Department of Pharmaceuticals.

Therefore, in exercise of powers, conferred by sub paragraph (3) and (4) of paragraph 11 of the Drugs (Prices Control) Order, 2013, read with S.O. 1394(E) dated the 30th May, 2013, S.O. 1192(E) dated 22nd March, 2016 issued by the Government of India in the Ministry of Chemicals and Fertilizers in so far as it relates to ringer lactate injection in pack having special features like (i) self collapsibility and self-sealability (ii) not having air-vent and (iii) there is no chance of contamination during manufacture / infusion/admixing levels, manufactured by the manufacturers specified in Table 'B', 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 with the dosage form & strength and unit/packaging specified respectively in the corresponding entries in columns (3) and (4) thereof:

Sl. No.	Name of the Scheduled Formulation	Dosage form and Strength	Unit	Ceiling Price excluding GST (Rs.)
(1)	(2)	(3)	(4)	(5)
1	Ringer lactate	Injection100 ml	Each 100 ml pack having special features	23.51
2	Ringer lactate	Injection 250 ml	Each 250 ml pack having special features	40.08

Table 'A'

3	Ringer lactate	Injection 500 ml	Each 500 ml pack having special features	51.07
4	Ringer lactate	Injection 1000 ml	Each 1000 ml pack having special features	89.77

Table 'B'

Sl. No.	Name of Manufacturer	
(1)	(2)	
1	M/s Albert David Ltd	
2	M/s Aculife Healthcare Pvt. Ltd	
3	M/s B. Braun Medical (India) Pvt. Ltd	
4	M/s Fresenius Kabi India Pvt. Ltd	
5	M/s Ostuka Pharmaceuticals India Pvt. Ltd	

Note:

(a) All the existing 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 their 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) 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.

(c) The manufacturer shall issue a price list in Form-V in compliance from date of this notification as per paragraph 24 of the DPCO, 2013.

(d) 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.

(e) Any other manufacturer claiming separate ceiling price for ringer lactate injection in pack having special features like (i) self collapsibility and self-sealability (ii) not having airvent and (iii) there is no chance of contamination during manufacture / infusion/admixing levels shall apply to NPPA for separate ceiling price approval.

(f) For other special features claimed or any other pack size manufactured, the manufacturer shall approach the NPPA for specific price approval for its formulation.

(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 (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. Any manufacturer intending to discontinue production of above said scheduled formulation shall furnish information to the NPPA, in respect of discontinuation of the 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 (Price Control) Order, 2013 read with Essential Commodities Act, 1955.

(j) Consequent to the issue of ceiling prices of such formulations for specified in column (2) of the above Table A 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/205/73/2020/F

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