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Extraordinary)

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

New Delhi, the 1st April 2017

S.O. 1051 (E)- In exercise of powers, conferred by sub paragraph (3) and (4) of paragraph 11 and paragraph 14 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 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 1993(E) dated 3rd June,2016 read with Corrigendum order S.O 2062 dated 9th June, 2016, S.O 2210(E) dated 24th June 2016, S.O 2578(E) dated 1st August 2016, S.O. 3161(E) dated 6th October 2016 in so far as they relate to formulation packs of Non-Glass with special features (mentioned as Non-PVC in S.O. 1993(E) dated 3rd June 2016) mentioned in the **Table A** herein 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 2016 as specified in column (5) of the **Table A** herein below as separate ceiling price exclusive of local 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) @ 1.97186% increase.

| SI No | Medicines | Dosage form and Strength | Unit/packaging | Ceiling price (wef 01.4.2017 with WPI @ 1.97186%) |
|-------|-----------------------------------|-----------------------------|--|---|
| (1) | (2) | (3) | (4) | (5) |
| 1 | Glucose (A) + Sodium Chloride (B) | Injection 5% (A) + 0.9% (B) | 1000ml Non Glass with special features | 75.96 |
| 2 | Glucose (A) + Sodium Chloride (B) | Injection 5% (A) + 0.9% (B) | 500ml Non Glass with special features | 64.99 |
| 3 | Glucose | Injection 5% | 1000ml Non Glass with special features | 72.28 |
| 4 | Glucose | Injection 5% | 500ml Non Glass with special features | 62.53 |
| 5 | Sodium Chloride | Injection 0.9% | 1000ml Non Glass with special features | 74.86 |
| 6 | Sodium Chloride | Injection 0.9% | 100ml Non Glass with special features | 31.97 |
| 7 | Sodium Chloride | Injection 0.9% | 250ml Non Glass with special features | 47.19 |
| 8 | Sodium Chloride | Injection 0.9% | 500ml Non Glass with special features | 66.84 |

TABLE 'B'

| Sl. No. | Name of Manufacturer | Product /Brand Name |
|---------|----------------------------------|-----------------------------------|
| (1) | (2) | (3) |
| 1 | M/s B.Braun Medical (I) Pvt Ltd. | Ecoflac Plus bottle with Eurohead |
| 2 | M/s Amanta Healthcare Ltd. | Steriport bottle |
| 3 | M/s Aculife Healthcare Pvt Ltd. | Aculife bottle with Eurohead |

| | | |
|----|--|-----------------------------------|
| 4 | M/s Albert David Limited | Albert David bottle with Eurohead |
| 5 | M/s Denis Chem Limited | Aquapulse with Eurohead |
| 6 | M/s Claris Life Sciences Limited | Claris bottle with Eurohead |
| 7 | M/s Fresenius Kabi India Pvt Limited | Freeflex bags |
| 8 | M/s Otsuka Pharmaceutical India Private Ltd. (previously known as Claris Otsuka Private Limited) | Unibag |
| 9 | M/s Aishwarya Lifesciences | Lifusion Eurohead bottle |
| 10 | M/s Baxter (India) Pvt. Ltd. | Viaflex bags |
| 11 | M/s Claris Otsuka Private Limited | Eurohead bottle |
| 12 | M/s Fresenius Kabi India Pvt Limited | Eurohead bottle |

- (a) The ceiling prices are applicable with effect from 01.4.2017 (ceiling prices are inclusive of Wholesale Price Index (WPI) @1.97186% for the year 2016 over 2015).
- (b) The manufacturers of scheduled formulations, selling abovesaid products/brandname of scheduled formulations at 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.
- (c) The 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), may revise the existing M.R.P. of their formulations, on the basis of WPI @ 1.97186% for year 2016 in accordance with paragraph 16(2) of DPCO, 2013, read with para 13(2) of DPCO, 2013.
- (d) 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.
- (e) Any other manufacturer claiming separate ceiling price for Non-Glass with special feature shall apply to NPPA for separate ceiling price approval with details and demonstrate, that such pack has all of the features as (i) self collapsibility and self-sealability (ii) not having air-vent; and (iii) there is no chance of contamination during manufacture/ infusion/ admixing levels alongwith documentation and demonstration.
- (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) 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 (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.
- (l) 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/175/43/2017/F

F. No. 8(43)/2017/D.P./NPPA-Div.II

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