(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

New Delhi, the 23rd January, 2018

ORDER

S. O.-**353(E)** In exercise of the powers conferred by paragraphs 5, 11 and 15 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, the National Pharmaceutical Pricing Authority (hereinafter referred as NPPA), hereby fixes, the price as specified in column (6) of the table herein below as the retail price, exclusive of goods and services tax, if any, in relation to the formulation specified in the corresponding entry in column (2) of the said Table with the strength, unit and name of manufacturer & marketing company, as specified in the corresponding entries in columns (3), (4) and (5) thereof;

Table

| Sl. No. | Name of the Scheduled Formulation / Brand Name | Strength | Unit | Manufacturer & Marketing Company | Retail Price (Rs.) |
|------------|---|---|--------------|--|--------------------------|
| (1) | (2) | (3) | (4) | (5) | (7) |
| 1. | Olmesartan Medoxomil + Amlodipine + Hydrochlorothiazide Tablet | Each film coated tablet contains: Olmesartan Medoxomil IP 40mg Amlodipine Besylate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg | 1 Tablet | M/s Akums Drugs and Pharmaceutical Ltd. / M/s Zuventus Healthcare Limited | 13.88 |
| 2. | Olmesartan Medoxomil + Amlodipine + Hydrochlorothiazide Tablet | Each film coated tablet contains: Olmesartan Medoxomil IP 20mg Amlodipine Besylate IP eq. to Amlodipine 5mg Hydrochlorothiazide IP 12.5mg | 1 Tablet | M/s Akums Drugs and Pharmaceutical Ltd. / M/s Zuventus Healthcare Limited | 9.15 |
| 3. | Tiotropium Bromide + Formoterol Fumarate + Ciclesonide Powder for Inhalation | Each capsule contains: Tiotropium (as Tiotropium Bromide Monohydrate) 18mcg Formoterol Fumarate Dihydrate 12mcg | 1 Capsule | M/s Lupin Ltd. | 14.67 |

| | | Ciclesonide 400mcg | | | |
|----|---|---|----------|---|-------|
| 4. | Isosobide Dinitrate + Hydralazine HCl tablet (Sorbitrate HF) | Each film coated tablet contains: Diluted Isosorbide Dinitrate eq. to Isosorbide Dinitrate 20mg Hydralazine | 1 Tablet | M/s Windlas Biotech Ltd. / M/s Abbott Healthcaere Pvt. Ltd. | 5.61 |
| 5. | Olmesartan Medoxomil + Amlodipine + Tablet | Hydrochloride 37.5mg Each film coated tablet contains: Olmesartan Medoxomil IP 40mg Amlodipine Besylate IP eq. to Amlodipine 5mg | 1 Tablet | M/s Synokem Pharmaceuticals Ltd. / M/s Zuventus Healthcare Limited | 12.87 |

Note:

- (a) The manufacturer of above mentioned formulations i.e. "new drug" under paragraph 2(u) of the DPCO, 2013 shall fix the retail price as specified in column (6) of the table hereinabove.
- (b) The manufacturer may add goods and services tax only if they have paid actually or it is payable to the Government on the retail price mentioned in column (6) of the above said table.
- (c) The retail price for a pack of the aforesaid formulation shall be arrived at by the concerned manufacturer in accordance with the retail price specified in column (6) of the above table as per provisions contained in paragraph 11 of the DPCO, 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.
- (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) The above mentioned retail price is applicable only to the individual manufacturer / marketeer as mentioned above i.e. who have applied for the same by submitting Form-I for price fixation / revision as stipulated under DPCO, 2013 and subject to fulfilment of all the applicable statutory requirements as laid down by the Govt. under relevant statutes/ rules, including manufacturing license permission from the Competent Authority i.e. the Central/State Licensing Authority, as may be applicable, by the concerned manufacturer/marketing companies.
- (f) The concerned manufacturer of above said formulations shall furnish quarterly return to the NPPA, in respect of production / import and sale of product in Form-III of Schedule-II of the DPCO, 2013 through IPDMS. Manufacturer, in case intending to discontinue above said formulations, shall furnish information to the NPPA, in respect of discontinuation of the production and / or import of above said formulation in Form-IV of Schedule-II of the DPCO, 2013 at least six months prior to the intended date of discontinuation.

- (g) In case the retail price of any of the aforesaid formulations is not complied with, as per instant price notification and notes specified hereinabove, then the concerned manufacturer/marketing company shall be liable to deposit the overcharged amount along with the interest thereon under the provisions of the DPCO, 2013 read with the Essential Commodities Act, 1955.
- (h) 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.

PN/185/53/2017/F

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