

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

New Delhi, the 18th December, 2019

ORDER

S.O. - Whereas the National Pharmaceutical Pricing Authority (NPPA) was established vide the Resolution of the Government of India in the Ministry of Chemicals and Fertilizers No. 33/7/97-PI.I dated 29th August, 1997, inter-alia, to fix prices and notify the changes therein, if any, of bulk drugs and formulations, monitor the prices of non-scheduled drugs and formulations and oversee the implementation of the provisions of the Drugs (Price Control) Order (DPCO).

2. And whereas the Ministry of Chemicals and Fertilizers vide S.O.1394 (E) dated the 30th May, 2013, in exercise of the powers conferred by Section 3 and 5 of Essential Commodities Act, 1955 has delegated the powers in respect of specified paras of the DPCO, 2013, including para 11(3) of the said Order to be exercised by the NPPA on behalf of the Central Government.

3. And whereas NPPA had received an application/ representation from M/s Glenmark Pharmaceuticals Ltd for separate price of 'digital dose counter' under the brand "Digihaler" for its formulation (a) Budesonide 100mcg+ Formeterol 6mcg per dose Inhaler 120 MDI (b) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (c) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI having digital dose counter.

4. And whereas, the application of M/s Glenmark Pharmaceuticals Ltd was placed before the Multidisciplinary Committee of Experts in its 14th meeting dated 04.12.2019. Two Pharmacoeconomic experts were co-opted in the Committee. The Committee noted that a separate price could be considered to promote incremental innovation. Accordingly, it recommended special price of 'digital dose counter' under the brand "Digihaler" for M/s Glenmark Pharmaceuticals Ltd under para 11(3) of DPCO 2013.

5. And whereas, NPPA in its 71st meeting dated 09.12.2019 deliberated upon the applications/ representations of M/s Glenmark Pharmaceuticals Ltd and accepted the recommendations of the Multidisciplinary Committee of Experts to give separate price of 'digital dose counter' under the brand "Digihaler" for M/s Glenmark Pharmaceuticals Ltd under para 11(3) of DPCO 2013.

6. Therefore, in exercise of powers, conferred by paragraph 11(3) of the Drugs (Prices Control) Order, 2013, read with S.O. No. 1394(E) dated the 30th May, 2013 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 price, exclusive of goods and services tax, if any, in relation

to the device specified in the corresponding entry in column (2) of the said Table with the brand, unit and name of company, as specified in the corresponding entries in columns (3), (4) and (5) thereof;

Table

| Sl. No. | Name of the device | Brand | Unit | Company | Price (Rs.) |
|---------|----------------------|-----------|----------|----------------------------------|-------------|
| (1) | (2) | (3) | (4) | (5) | (6) |
| 1 | Digital Dose Counter | Digihaler | Per Unit | M/s Glenmark Pharmaceuticals Ltd | Rs. 44.70 |

Note:

- (a) The device as specified in column in (2) of the above said table would be applicable to the formulation (a) Budesonide 100mcg+ Formeterol 6mcg per dose Inhaler 120 MDI (b) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (c) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI of M/s Glenmark Pharmaceuticals Ltd having digital dose counter.
- (b) M/s Glenmark Pharmaceuticals Ltd may add the price as specified in column (6) of the above said table to the ceiling price, as applicable, of the formulation (a) Budesonide 100mcg+ Formeterol 6mcg per dose Inhaler 120 MDI (b) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (c) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI of M/s Glenmark Pharmaceuticals Ltd having digital dose counter.
- (c) M/s Glenmark Pharmaceuticals Ltd may add goods and services tax only if they have paid actually or it is payable to the Government on the price mentioned in column (6) of the above said table.
- (d) M/s Glenmark Pharmaceuticals Ltd 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) The price of the digital dose counter as specified in column (6) of the above said table would remain fixed irrespective of the subsequent change in the ceiling price of the formulation (a) Budesonide 100mcg+ Formeterol 6mcg per dose Inhaler 120 MDI (b) Budesonide 200mcg+ Formeterol 6mcg per dose Inhaler 120 MDI and (c) Budesonide 400mcg+ Formeterol 6mcg per dose Inhaler 120 MDI of M/s Glenmark Pharmaceuticals Ltd having digital dose counter.
- (f) 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.
- (g) The above mentioned price of the device is applicable only to M/s Glenmark Pharmaceuticals Ltd 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.

- (h) M/s Glenmark Pharmaceuticals Ltd shall furnish quarterly return to the NPPA, in respect of production / import and sale of the device with the formulation as stated hereinabove 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.
- (i) In case the price of the device is not complied with, as per instant price notification and notes specified hereinabove, then M/s Glenmark Pharmaceuticals Ltd 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.

PN/203/71/2019/F

F. No. 8(71)/2019/ DP/Div-II/NPPA

(Prasenjit Das)
Asst. Director