

856(E)

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

New Delhi, the 25th March, 2015

ORDER

S.O. 856(E)- 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-Pl.I dated 29th August, 1997 inter alia, to fix prices and notify the changes therein, if any, of bulk drug 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).

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 32 of the said order to be exercised by the NPPA on behalf of the Central Government.

And whereas an application received from M/s Torrent Pharmaceuticals Limited, Ahmadabad for non-application of provisions of DPCO, 2013 under para 32 (iii) of the said order in respect of Olanzapine Pamoate Prolong Release Powder for suspension for IM Injection (Olanzapine Pamoate Monohydrate equivalent to Olanzapine 210 mg/vial, 300 mg/vial and 405 mg/vial) duly approved by the office of Drugs Controller General (India) as 'new drug' under Rule 122(E) of the Drugs and Cosmetic Act and Rules thereunder, was examined by the Expert Committee constituted for this purpose.

And whereas the NPPA has considered the recommendations of the Expert Committee in detail at its 153rd meeting held on 25.03.2015 and approved that Olanzapine Pamoate Prolong Release Powder for suspension for IM Injection (Olanzapine Pamoate Monohydrate equivalent to Olanzapine 210 mg/vial, 300 mg/vial and 405 mg/vial) of M/s Torrent Pharmaceuticals Limited, Ahmadabad qualifies for the non-application of provisions of DPCO, 2013 under para 32 (iii) of the said Order for a period of 5 years from the date of its marketing approval in India.

Now, therefore, in exercise of the powers delegated under para 32 of the Drugs (Prices Control) Order, 2013 vide S.O. No. 1394(E) dated 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers NPPA allow M/s Torrent Pharmaceuticals Limited, Ahmadabad to avail non-application of the provision of DPCO, 2013 under para 32 (iii) of the said order in respect of above said drug viz. Olanzapine Pamoate Prolong Release Powder for suspension for IM Injection (Olanzapine Pamoate Monohydrate equivalent to Olanzapine 210 mg/vial, 300 mg/vial and 405 mg/vial) for a period of five years with effect from 14.10.2014, which is the date of grant of marketing approval by the Drugs Controller General (India).

The company shall inform NPPA of the maximum Retail Price fixed by the company in respect of above said drug by issuing a price list in form V under DPCO, 2013.

PN/153/21/2015/F

F.No. 23(6)/2014/ Div-III/NPPA

(NARESH ARYA)

Deputy Director