

2110(E)

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

New Delhi, the 21st August, 2014

ORDER

S.O.2110(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-PI.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 decontrolled 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 paragraphs of the DPCO, 2013, including paragraph 19 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 paragraph 32(iii) of the said order in respect of Fixed Dose Combination (FDC) of Prasugrel Hydrochloride 10mg (as film coated) plus Aspirin 75mg (as entric coated), duly approved by the office of Drugs Controller General (India) as 'new drug' under Rule 122(E) of 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 149th meeting held on 20.08.2014 and approved that the FDC of Prasugrel Hydrochloride 10mg (as film coated) plus Aspirin 75mg (as entric coated) of M/s. Torrent Pharmaceuticals Limited, Ahmadabad qualified for the non-application of provisions of DPCO, 2013 under paragraph 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 FDC for a period of five years with effect from 15.01.2014, which is the date of grant of marketing approval by the Controller General of India.

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

PN/149/17/2014/F

F. No. 23(6)/2013/Div-III/NPPA

(Injeti Srinivas)
Chairman
National Pharmaceutical Pricing Authority