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

New Delhi, the 31st December, 2020

ORDER

S. O. 4774(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 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 32 of the said order to be exercised by the NPPA on behalf of the Central Government.`

3. And whereas an application received from M/s Sun Pharmaceuticals Industries Limited, for exemption from the provisions of DPCO, 2013 under para 32 (i) of the said order in respect of Fixed Dose Combination (FDC) of Silver Sulfadiazine IP (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream which was duly approved by the Office of Central Drugs Standard Control Organisation (India) as 'new drug' under the Drugs and Cosmetics Act, 1940 and Rules thereunder. Further, the Patent office, India has granted Patent Certificate to M/s Sun Pharmaceutical Industries Ltd for an invention entitled 'A stable topical Pharmaceutical composition comprising Nanonized Silver Sulfadiazine' for the term of 20 years from 27th July 2016 in accordance with the provisions of the Patents Act, 1970 (Patent No. 349599 and Date of Grant: 20.10.2020).

4. And whereas the NPPA at its 82nd meeting dated 23.12.2020 noted that M/s Sun Pharmaceutical Industries Ltd meets the requirement of para 32(i) of DPCO 2013 and decided that exemption may be granted to M/s Sun Pharmaceutical Industries Ltd under para 32(i) of DPCO, 2013 for their product Fixed Dose Combination (FDC) of Silver Sulfadiazine IP (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream.

5. Now, therefore, in exercise of the powers delegated under para 32 of the Drugs (Prices Control) Order, 2013 vide S.O. 1394(E) dated 30th May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, M/s Sun Pharmaceuticals Industries Limited is exempted from the provisions of DPCO, 2013 under para 32 (i) of the said order in respect of above said drug viz. Fixed Dose Combination (FDC) of Silver Sulfadiazine IP (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country. Further, the period of five years is co-terminus with the duration of Indian Patent.

6. The company shall inform NPPA the date of commercial marketing of 'Fixed Dose Combination (FDC) of Silver Sulfadiazine IP (Nanonized) 0.5% w/w and Chlorhexidine Gluconate 0.2% w/w topical cream' in the country and the Price to Retailer (PTR) and Maximum Retail Price fixed by the company in respect of above said formulation by issuing a price list in Form V under DPCO, 2013.

PN/214/82/2020/F F. No. 8(82)/2020/ DP/Div-II/NPPA

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