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

New Delhi, the 28th February, 2020

ORDER

S.O. **910(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 Meril Life Sciences Pvt. Ltd, for exemption from the provisions of DPCO, 2013 under para 32 (ii) of the said order in respect of drug Coronary Stent namely "Sirolimus Eluting BioResorbable Vascular Scaffold System (MeRes100)" which was duly approved by the office of Central Drugs Standard Control Organisation (India) as 'new drug' under Rule 122(E) of the Drugs and Cosmetics Act and Rules thereunder, and patented by The Patent Office, India under the Patents Act, 1970 (Patent No. 296768 and Date of Grant: 14.05.2018).

4. And whereas the NPPA at its 73rd meeting dated 25.02.2020 noted that M/s Meril Life Sciences Pvt. Ltd meets the requirement of para 32(ii) of DPCO 2013 and decided that exemption may be granted to M/s Meril Life Sciences Pvt. Ltd under para 32(ii) of DPCO 2013 for their drug Coronary Stent namely "Sirolimus Eluting BioResorbable Vascular Scaffold System (MeRes100)".

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 Meril Life Sciences Pvt. Ltd is exempted from the provisions of DPCO, 2013 under para 32 (ii) of the said order in respect of above said drug Coronary Stent namely "Sirolimus Eluting BioResorbable Vascular Scaffold System (MeRes100)" for a period of five years from the date of the commencement of its commercial production in the country.

6. The company shall inform NPPA of the Maximum Retail Price fixed by the company in respect of above said formulation by issuing a price list in Form V under DPCO, 2013.

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F. No. 8(73)/2020/ DP/Div-II/NPPA

(Prasenjit Das) Asst. Director