

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

New Delhi, the 8<sup>th</sup> August, 2023

ORDER

S.O. 3561(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 29<sup>th</sup> 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 30<sup>th</sup> 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 Troikaa Pharmaceuticals Limited**, for exemption from the provisions of DPCO, 2013 under para 32 (i) of the said order in respect of the formulation "**Paracetamol Injection (Intramuscular) 250mg/ml, 2ml**" 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 there under. Further, the Patent Office, Government of India has granted Patent to **M/s Troikaa Pharmaceuticals Limited** for an invention entitled "**Novel Composition Comprising Paracetamol and Process for Preparing the same**" for the term of 20 years from 9<sup>th</sup> September 2010 in accordance with the provisions of the Patents Act, 1970 (Patent No. 411067 and Date of Grant: 09.11.2022).

4. And whereas the NPPA at its **115<sup>th</sup> meeting dated 31.07.2023** noted that **M/s Troikaa Pharmaceuticals Limited** meets the requirement of Para 32(i) of DPCO 2013 and decided that exemption may be granted to **M/s Troikaa Pharmaceuticals Limited** under Para 32(i) of DPCO, 2013 for their formulation "**Paracetamol Injection (Intramuscular) 250mg/ml**".

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 30<sup>th</sup> May, 2013 issued by the Government of India in the Ministry of Chemicals and Fertilizers, **M/s Troikaa Pharmaceuticals Limited** is exempted from the provisions of DPCO, 2013 under para 32 (i) of the said order in respect of the formulation "**Paracetamol Injection (Intramuscular) 250mg/ml**" for a period of five years from the date of commencement of its commercial marketing by the manufacturer in the country or expiry of the Indian patent, whichever may be earlier.

6. **M/s Troikaa Pharmaceuticals Limited** shall inform NPPA, the date of commercial marketing of the formulation "**Paracetamol Injection (Intramuscular) 250mg/ml**" 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.

7. **M/s Troikaa Pharmaceuticals Limited** shall also seek retail price approval for the formulation "**Paracetamol Injection (Intramuscular) 250mg/ml**", if applicable, three month before the expiry of the exemption granted under Para 32(i) of DPCO 2013