मिलि., 1400 मिग्रा./140 मिलि. और 1600 मिलि.ग्राम/160 मिलि. इन्फ्यूजन बैग्स का उपयोग करने के लिए तैयार है) का उपयोग करने के लिए छूट दी जा सकती है।

5. अब इसलिए का.आ 1394(अ), दिनांक 30 मई, 2013 को रसायन एवं उर्वरक मंत्रालय, भारत सरकार द्वारा जारी औषधि (मूल्य नियंत्रण) आदेश, 2013 के पैरा 32 के अन्तर्गत प्रदत्त शक्तियों का प्रयोग करते हुए, उपर्युक्त उक्त औषधि अर्थात देश में इसके वाणिज्यिक उत्पादन की शुरूआत की तारीख से पांच वर्ष की अवधि के लिए जेमसीटाबिन हाइड्रोक्लोराइड इंजेक्शन 10 मिग्रा./मिलि. का उपयोग करने के लिए इन्फ्यून बैग्स तैयार है (1200 मिग्रा./120 मिलि., 1400 मिग्रा./140 मिलि. और 1600 मिलि.ग्राम/160 मिलि. इन्फ्यूजन बैग्स का उपयोग करने के लिए तैयार है) के संबंध में उक्त आदेश के पैराग्राफ 32 (ii) के अन्तर्गत डीपीसीओ, 2013 के प्रावधानों से मैसर्स सन फार्मास्यूटिकल्स इंडस्ट्रीज को छूट दी गई है।

6. कम्पनी डीपीसीओ, 2013 के तहत फॉर्म V में मूल्य सूची जारी करके उक्त औषधि के बारे में कम्पनी द्वारा तय की गई अधिकतम खुदरा मूल्य एनपीपीए को सूचित करेगी।

[कां. सं./202/70/2019/एफ/फा. सं. 8(70)/2019/डीपी/एनपीपीए–डिवी-II]

प्रसेनजीत दास, सहायक निदेशक

ORDER

New Delhi, the 8th November, 2019

S.O. 4064(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 (ii) of the said order in respect of Ready to use infusion bags Gemcitabine Hydrochloride Injection 10mg/ml (Ready to use infusion bags 1200mg/120ml, 1400mg/140ml & 1600mg/160ml) 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. 296771 and Date of Grant: 14.05.2018).

4. And whereas the NPPA at its 70th meeting dated 30.10.2019 noted that M/s Sun Pharmaceutical Industries Ltd meets the requirement of para 32(ii) of DPCO 2013 and decided that exemption may be granted to M/s Sun Pharmaceutical Industries Ltd under para 32(ii) of DPCO, 2013 for their product Ready to use infusion bags Gemcitabine hydrochloride injection 10mg/ml (Ready to use infusion bags 1200mg/120ml, 1400mg/140ml and 1600mg/160ml).

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 (ii) of the said order in respect of above said drug viz. Ready to use infusion bags Gemcitabine Hydrochloride Injection 10mg/ml (Ready to use infusion bags 1200mg/120ml, 1400mg/140ml & 1600mg/160ml) for a period of five years from the date of the commencement of its commercial production in the country.

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

[PN/202/70/2019/F/F. No. 8(70)/2019/D.P./NPPA-Div.-II]

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