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

New Delhi, the 12th April, 2022

ORDER

S. O. 1783(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 Serum Institute of India Pvt. Ltd, for exemption from the provisions of DPCO, 2013 under Para 32 (ii) of the said order in respect of the formulation "Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent) (PCV 10V) in (i) single dose (0.5 ml) vial, (ii) multi-dose (5 dose-2.5 ml) vial, and (iii) single dose (0.5ml) pre-filled syringes 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 on 14.07.2020.

4. And whereas, the Patent Office, Government of India has granted Patent to M/s Serum Institute of India Pvt. Ltd for (i) an invention entitled 'PURIFICATION OF CAPSULAR POLYSACCHARIDES' for the term of 20 years from 15.05.2010 in accordance with the provisions of the Patents Act, 1970 (Patent No. 318780 and Date of Grant: 22.08.2019), (ii) an invention entitled 'A METHOD FOR PREPARING BACTERIAL VACCINES' for the term of 20 years from 26.04.2010 in accordance with the provisions of the Patents Act, 1970 (Patent No. 284211 and Date of Grant: 14.06.2017) and (iii) an invention entitled 'METHOD FOR EVALUATION OF MULTIPLE ANTIGENS' for the term of 20 years from 26.03.2010 in accordance with the provisions of the Patents Act, 1970 (Patent No. 276304 and Date of Grant: 13.10.2016).

5. And whereas the NPPA at its 96th meeting dated 24.03.2022 observed that M/s Serum Institute of India Pvt. Ltd meets the requirement of Para 32(ii) of DPCO 2013 and decided that exemption may be granted to M/s Serum Institute of India Pvt. Ltd under Para 32(ii) of DPCO, 2013 for their formulation "Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent) (PCV 10V)" in (i) single dose (0.5 ml) vial, (ii) multi-dose (5 dose-2.5 ml) vial), and (iii) single dose (0.5ml) pre-filled syringes.

6. 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 Serum Institute of India Pvt. Ltd is exempted from the provisions of DPCO, 2013 under para 32 (ii) of the said order in respect of the formulation "Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent) (PCV 10V)" in (i) single dose (0.5 ml) vial, (ii) multi-dose (5 dose-2.5 ml) vial), and (iii) single dose (0.5ml) pre-filled syringes for a period of five years from the date of commencement of its commercial

production in the country. Further, the period of five years is co-terminus with the duration of Indian Patent.

7. M/s Serum Institute of India Pvt. Ltd shall inform NPPA, the date of commercial production of the formulation "Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent) (PCV 10V)" in (i) single dose (0.5 ml) vial, (ii) multi-dose (5 dose-2.5 ml) vial), and (iii) single dose (0.5ml) pre-filled syringes 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.

8. M/s Serum Institute of India Pvt. Ltd shall also seek retail price approval for the formulation ""Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (10-Valent) (PCV 10V)" in (i) single dose (0.5 ml) vial, (ii) multi-dose (5 dose-2.5 ml) vial), and (iii) single dose (0.5ml) pre-filled syringes, if applicable, three month before the expiry of the exemption granted under Para 32(ii) of DPCO 2013

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