Recommendations of the SEC (COVID-19) made in its 02nd/24 meeting held on 29.04.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	File No: BIO/MA/23/000137 COVID-19 Vaccine, Adjuvanted 2023-2024 Formula [SARS-CoV-2 rS Protein (COVID-19) Nanoparticle Vaccine, Omicron XBB.1.5 variant]	M/s. Serum Institute of India Pvt. Ltd.	The firm presented the proposal for the grant of permission to manufacture COVID-19 Vaccine, Adjuvanted 2023-2024 Formula [SARS-CoV-2 rS Protein (COVID-19) Nanoparticle Vaccine, Omicron XBB.1.5 variant] for sale and distribution in India for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older. The firm presented the preclinical studies reports along with interim report of ongoing clinical trial in USA to evaluate the safety and immunogenicity of a XBB.1.5 booster dose in previously mRNA COVID-19 vaccinated and baseline SARS-CoV-2 seropositive COVID-19 vaccine naïve participants before the committee. The committee noted the following: (A) Non-Clinical Studies: Pre-clinical immunogenicity studies were performed in mice and rhesus macaques to determine the immunogenic response of bivalent and monovalent COVID-19 vaccines containing Omicron variants including BA.2, BA.5 and XBB.1.5, as a primary vaccination series followed by booster dosing with XBB.1.5. 1. The study results demonstrated comparable antibody-mediated immune response against XBB.1.5, and other variants. 2. The study in rhesus macaques also demonstrated the immunogenicity of COVID-19 vaccine (Omicron XBB1.5) as a booster dose to neutralize different circulating variants including the JN1 variant.

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			(B) The approved vaccine is manufactured by M/s Serum Institute of India Pvt. Ltd. (SIIPL), Pune under technology transfer from Novavax and is approved by USFDA under emergency use authorization, European Medicines Agency (EMA), MHRA, Health Canada, Brazil, Taiwan & has also received recommendation of WHO for the emergency use listing of COVID-19 XBB 1.5 vaccine. (C) The committee also noted the interim report of the ongoing clinical trial in USA that: (i) the co-primary endpoints of the study were achieved, as the Omicron XBB.1.5 subvariant vaccine (NVX-CoV2601) induced a superior neutralizing antibody response in GMT (ID_{50}) against the Omicron XBB.1.5 subvariant virus along with a non-inferior SRR versus the prototype (Wuhan) Novavax vaccine at day 28 following booster administration in participants previously vaccinated with $\geq$ 3 doses of prototype or bivalent COVID-19 mRNA vaccines. (ii) NVX-CoV2601 was well tolerated, with an acceptable safety profile when used as heterologous booster who had previously received prototype monovalent and/or BA.4/5 containing bivalent mRNA vaccines. (D) Approximately, 42 million doses have been exported to USA and Europe till date and 200,000 vaccine doses have already been administered to the vaccinees in the USA with no safety concern till date. (E) (a) Risk versus benefit- The safety profile of the vaccine from preclinical and clinical studies conducted globally justify the grant of permission.

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			(b) Innovation vis-a-vis existing therapeutic- COVID-19 continues to be a global health challenge with important genetic and antigenic evolution of the spike protein. The vaccine elicits broadly cross-reactive neutralizing antibody responses against circulating SARS-CoV-2 variants. (c) Unmet medical need in the country- Presently, there is no vaccine with XBB 1.5 strain approved in the country. After detailed deliberation, based on the above observations, the committee recommended for strain change in the approved COVID-19 vaccine and grant of permission of the COVID-19 Vaccine, Adjuvanted 2023-2024 Formula [SARS-CoV-2 rS Protein (COVID-19) Nanoparticle Vaccine, Omicron XBB.1.5 variant] with local clinical trial waiver, for restricted use in emergency situation, subject to various regulatory provisions including following: 1. To conduct a Phase IV study in the country. Accordingly, Phase IV study protocol shall be submitted within three months. 2. The vaccine is indicated for active immunization to prevent COVID – 19 disease (a) in individuals of ≥ 12 to < 18 years of age as primary series of two doses (0.5mL each) 3 weeks apart (b) as single precautionary dose in individuals of ≥ 18 years of age, who have received primary series of vaccinations 3. Firm should submit revised PI, SmPC & Factsheet to CDSCO

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			after incorporating the latest safety & immunogenicity data and the suggestions made during the meeting. 4. The vaccine should be supplied along with factsheet & separate leaflet for the guidance of the healthcare provider. 5. The firm should ensure that factsheet for the vaccine recipient / attendant is provided prior to administration of the vaccine. 6. The firm should disseminate the instructions & educational material including factsheet, PI, SmPC, storage instructions etc. in their website. 7. The firm should submit safety, efficacy & immunogenicity data from the ongoing clinical trials in India & overseas for review as and when available. 8. The firm should submit safety data including the data on AEFI and AESI with due analysis as per the provisions and standard procedures. 9. The firm should submit India specific Pharmacovigilance and Risk management plan.
FDC Division			
2.	FDC/MA/22/000207 Four Tablets of Nirmatrelvir 150mg tablets + Two tablets of Ritonavir 100mg tablet, Co-packaged	M/s. Mylan Laboratories Limited	The firm presented their proposal along with BE study report conducted for export purpose and animal toxicity study data before the committee. The committee noted that the Combipack of Nirmatrelvir 300mg tablets (2x150mg tablets) and Ritonavir tablets 100mg is already approved by CDSCO on 21.04.2022.

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			After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed Combipack.