Recommendations of the SEC (COVID-19) made in its 02nd/25 meeting held on 04.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Vaccine Division			
1.	BIO/CT/25/000083 SARS-CoV-2 (Covid-19) Vaccine (Variant JN.1)	M/s Biological E Ltd	Firm presented Phase III clinical trial protocol titled "A prospective single-blind randomized Phase-III comparative study to evaluate immunogenicity and safety of Biological E's JN.1-RBD subunit Covid-19 vaccine in 18-80 years old individuals." The committee noted that: 1. Firm has conducted pre-clinical toxicity and immunogenicity studies with SARS-CoV-2 (Covid-19) Vaccine (Variant JN.1). 2. CORBEVAX vaccine with variant SARS-CoV-2-RBD219 N1C1 (ancestral strain) is approved for restricted use in emergency situation for age group 5 years and above in two dose schedule i.e. day 0 & day 28 and the vaccine is also approved as heterologous booster dose to individuals previously vaccinated with COVAXIN/COVISHIELD. 3. COVID-19 Vaccine SARS-CoV-2-RBD203-N1_XBB.1.5 (Corbevax) (XBB 1.5 Strain) was also approved by CDSCO under restricted use in emergency situation for active immunization to prevent COVID–19 disease in individuals of 5 years of age and above who have received primary vaccination series & to be administered in two dose schedule (0.5mL each) 28 days apart (Day 0 & Day 28). After detailed deliberation, the committee recommended that the proposed clinical trial design should include safety follow-up till 8 weeks and cross Neutralization studies on VoCs (LP.8.1) as exploratory objectives. Accordingly, firm should submit revised protocol to CDSCO.
2.	BIO/CT/25/000066 Trivalent Nanoparticle Influenza (tNIV)	M/s SERUM INSTITUTE OF INDIA PVT. LTD	Firm presented Phase II/III clinical trial protocol titled "Phase II/III, multicentre, observer-blind, randomized, active-controlled study to evaluate

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	Vaccine and Covid Trivalent Influenza Combination (CIC) Vaccine		immunogenicity and safety of a Trivalent Nanoparticle Influenza Vaccine and Covid-Influenza combination vaccine compared with Licensed Influenza and Covid-19 Vaccines in adults" The committee noted the following: 1. COVID-19 Vaccine, Adjuvanted 2023-2024 Formula [SARS-CoV-2 rS Protein (COVID-19) Nanoparticle Vaccine, Omicron XBB.1.5 variant] COVOVAX was approved for restricted use in emergency situation and 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 vaccination". 2. SARS-CoV-2 rS Protein (COVID-19) Nanoparticle Vaccine, JN.1 variant] of M/s Novovax, USA is approved by USFDA and indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by (SARS-CoV-2) in adults aged 65 years and older. Additionally, the vaccine is indicated "for individuals 12 through 64 years who have at least one underlying condition that puts them at high risk for severe outcomes from COVID-19". 3. During the Covid 19 pandemic, SIIPL manufactured and distributed >200 million doses of COVOVAX which is a vaccine based on Novavax's insect cell based baculovirus platform, globally and currently proposed Trivalent Influenza Nanoparticle Vaccine (tNIV) and Covid Influenza Vaccine Combination (CIC) are based on the same platform. CIC vaccine formulation contains both the SARS-CoV-2 and Influenza antigens.

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			4. Firm has conducted pre-clinical immunogenicity studies with Quadrivalent Influenza Nanoparticle Vaccine, SARS-CoV-2 rS (Wuhan Hu-1) strain with adjuvant Matrix M and with co-administered vaccine of Influenza and Covid 19. 5. Novavax has completed three clinical trials in more than 4300 participants for assessment of safety and immunogenicity of nanoparticle influenza vaccine (tNIV/qNIV) as follows: (a) Phase I/II studies (Trivalent Nanoparticle Influenza Vaccine in the age group >60 years in US; (b) Phase II and Phase III (Quadrivalent Nanoparticle Influenza Vaccine in age group of >65 years in US . These trials demonstrated that tNIV/qNIV is safe and immunogenic. Various doses of different antigen content were tested in these trials and all doses were found safe 6. Novavax has completed clinical trials in more than 2100 participants for assessment of safety and immunogenicity of Covid-Influenza combination (CIC) Vaccine as follows : (a) Phase I/II studies of Quadrivalent Nanoparticle Influenza Vaccine + SARS-CoV-2 rS (Wuhan) Nanoparticle COVID-19 vaccine (Covovax) in the age group of > 50-70 years in Australia (b) Phase II study of Quadrivalent Nanoparticle Influenza Vaccine + SARS-CoV-2 rS Nanoparticle COVID-19 vaccine (Covovax) in the age group of > 50-80 years Australia These trials demonstrated that CIC is safe and immunogenic. Various doses of different antigen content of SARS-CoV-2rs and recombinant hemagglutinin were tested in these trials and all doses were found safe 7. Novavax has received US-FDA approval for the Phase III clinical trial of Quadrivalent Nanoparticle

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			Influenza Vaccine + SARS-CoV-2 rS Nanoparticle COVID-19 vaccine (Covovax) in the age group of >65 years which is ongoing in Australia and New Zealand . 8. The investigational products used in all these trials are being manufactured by SIIPL. 9. Based on the PhaseI/II and Phase II studies in which various combination of antigen content of Influenza Strains and SARS-CoV-2 rs are studied and evaluated, the proposed formulation of Trivalent Influenza Nanoparticle Vaccine, Covid Influenza Combination vaccine have been selected for conduct of Phase II/III clinical trial in India After detailed deliberation, the committee recommended the following: 1. The study should be designed as four arm study with Covid Trivalent Influenza Combination (CIC) Vaccine, Trivalent Influenza Nanoparticle Vaccine, SARS-CoV-2 rs (JN.1 variant) and Fluquad. 2. Sample size of participants should be increased as per statistical calculation in proposed four arms with age stratification so that high risk population (more than 55 years of age group) is appropriately considered for safety and immunogenicity analysis. 3. Cross neutralization against VoCs for Covovax JN.1 alone and in CIC, immunogenicity persistence studies, efficacy end-points for hospitalization or severe COVID-19 cases should be part of exploratory objectives. Accordingly, the firm should submit revised protocol for further deliberation.

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New Drugs Division			
3.	ND/CT/20/000072 Remdesivir for Injection 100 mg/ vial	M/s JSS Medical Research Asia Pacific Private Limited	The firm did not turn up for the presentation.