Recommendations of the SEC (COVID-19) made in its 03rd/25 meeting held on 20.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Vaccine Division			
1.	BIO/CT/25/000066 Trivalent Nanoparticle Influenza (tNIV) Vaccine and Covid Trivalent Influenza Combination (CIC) Vaccine.	M/s Serum Institute of India Pvt. Ltd.	In light of recommendation of SEC dated 04.06.2025, firm presented revised protocol titled "A Phase II/III, multi-centre, observer-blind, randomized, active-controlled study to evaluate immunogenicity and safety of a Trivalent Nanoparticle Influenza Vaccine and Covid Influenza combination vaccine compared with licensed Influenza and COVID - 19 vaccines in adults" (version 3.0 dated 12.06.2025). The committee noted the following: - 1. The revised protocol was designed as four arm study with Covid Trivalent Influenza Combination (CIC) Vaccine, Trivalent Influenza Nanoparticle Vaccine, SARSCoV-2 rs (JN.1 variant) and Fluquad. 2. Sample size of participants was 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 severe COVID19 cases were included as exploratory objectives in the revised protocol. In view of above and after detailed deliberation, the committee recommended for conduct of proposed Phase II/III clinical trial as per presented revised protocol with condition that: 1. Women participants should be minimum 30 % in both age strata 2. (a) Vaccine should demonstrate cross-

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			protection ability against prevalent strains of SARS-CoV-2 and influenza (as notified by WHO / circulating widely in India) during Phase III study (b) The firm should specify the criteria for defining severe COVID - 19 infection as per current national guidelines for uniform implementation across sites for study outcome. Accordingly, firm should submit revised protocol to CDSCO. 3. The firm should submit study report of Phase II along with DSMB recommendation to CDSCO for review before proceeding to Phase III study.