Minutes of the Meeting of Subject Expert Committee (SEC) - Vaccine to review proposals and advice Drugs Controller General (India) in matters for Biologicals & PAC proposals held on 28.04.2026 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 28.04.2026 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1.	Recombinant, Influenza Vaccine (rIV) Phase I/II clinical trial protocol BIO/CT/26/000041	M/s Syngene International Limited	Firm has submitted application for conduct of Phase I/II clinical trial of Cell-Derived, Adjuvanted, Quadrivalent , Recombinant, Influenza Vaccine titled "A seamless, randomized, double-blind, placebo-controlled single-center Phase I study in healthy Indian adult participants followed by an active comparator controlled, multi-centric Phase II open label study in healthy adult participants and an elderly population to evaluate the safety, reactogenicity, and immunogenicity of Mynflu001, a recombinant, adjuvanted Influenza Vaccine" along with report of Phase I clinical study conducted in Australia. The committee noted the following: 1. The firm has submitted following studies report in animals: a) Repeated Dose Toxicity Study in Sprague Dawley rats and the vaccine was found to be safe for intramuscular administration. b) H3N2 strain efficacy study in ferrets with the higher concentration vaccine candidates showed efficacy against the challenge virus infection with regards to reduction in pathology. c) The firm has informed that efficacy studies have been conducted in mice, guinea pigs and hamsters and study reports are under preparation. As per the summary report the efficacy studies were conducted as comparability and challenge studies between the candidate

			vaccine and available egg based vaccine and in all cases the candidate vaccine showed better immunogenicity, though not statistically significant. d) An efficacy study conducted in non-human primates (Macaca mulatta) found the vaccine to be immunogenic in the in-vitro test. e) In all cases the booster dose has produced higher immunogenicity and protection. f) The firm has not conducted toxicity study in animal with doses higher than the human dose to establish NOAEL/ MABEL. 2. A randomized, double-blind, placebo-controlled, Phase I study in 46 healthy adults of age group 18-59 years was completed in Australia as a 2 dose regimen in two dose strengths with the primary objective of the study as safety and reactogenicity and secondary objective as immunogenicity. Based on safety and immunogenicity outcome of the Quadrivalent vaccine compared to the placebo, it was concluded that this study supports the safety, tolerability, and immunogenetic response of Mynflu001 as suitable for further clinical development. 3. The dose strengths and dose schedule proposed in the Indian study are different from that concluded in Australia. 4. The study in India is planned in 36 healthy adults with 2 dose strengths in the age group of 18 to 45 years in the Phase I part and a two-cohort Phase II trial in 90 healthy adults in age group of 18-59 years with 2 dose schedule based on dose selected from the

			Phase I study and with two different dose strengths as 2 dose schedule in 36 healthy adults in the age group of 60-75 years. 5. The firm has proposed that upon completion of Day 43 for all Phase I participants, the immunogenicity data at Day 43 will determine recommended Phase II dose (RP2D) for the Phase II healthy participant cohort and this will be presented to the DSMB before proceeding to Phase II part. In view of above and after detailed deliberation, the committee recommended that I. The firm should submit the complete animal study report and with dose higher than the human dose, if any. II. Firm should submit the Phase I report along with DSMB recommendation to CDSCO for review before proceeding to the Phase II part. III. The objectives and endpoints of the Phase I and Phase II trial for safety and immunogenicity should be clearly segregated in the protocol. IV. The firm has conducted SCR and SPR till day 85 in the Australian FIH study. Therefore, SCR and SPR should be measured at day 84 and day 180 for each strain besides GMT of HA Inhibition antibodies, IgG and neutralizing antibodies in the proposed study to assess the immune response. V. Firm has not defined any statistical hypothesis in Phase II part of the protocol for proceeding to the next Phase of clinical development

			program. Accordingly, the firm should submit revised protocol for further deliberation.
2	Live Attenuated Tetravalent Recombinant Dengue Vaccine -freeze dried Revised Phase II Clinical trial protocol [BIO/CT/25/000131] (Re-deliberation)	M/s. Indian Immunologicals Limited	In light of SEC (Vaccine) recommendation dated 27.10.2025, firm presented revised Phase II clinical trial protocol titled "A double-blind randomized multicentric placebo-controlled Phase II clinical trial to evaluate the safety and immunogenicity of two formulations of live attenuated tetravalent recombinant dengue vaccine of HBI in healthy participants". After detailed deliberation, the committee recommended for conduct of study as per the presented protocol.
3	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted) New Drug Permission [BIO/IMP/24/000133] (Re-deliberation)	M/s. GSK Pharma	In light of recommendation of SEC(Vaccine) dated 25.11.2025, firm presented the stratified data of older adults ≥60 years of age along with the six months safety data. After detailed deliberation, the committee recommended for grant of new drug permission.
4	Combined Tetanus Toxoid, Reduced Diphtheria Toxoid, Reduced Recombinant Pertussis vaccine (Tdap$_{gen}$) New drug permission [BIO/IMP/25/000063] (Re-deliberation)	M/s Techinvention Lifecare Limited	In light of recommendation of SEC dated 25.07.2025, firm presented revised report of Phase III clinical trial with following information: • Age stratified data in three cohorts wherein the firm inferred superiority of the vaccine w.r.t comparator without formal statistical power. • Immunogenicity data as per the three criteria defined under the primary objectives Further the committee noted that • as per the SmPC of the country of origin (Thailand), the vaccine

			(Tdapgen) is approved as Boostagen$_{RED}^{TM}$ for active booster immunization against tetanus, diphtheria and whooping cough in individuals from the age of 9 years onwards, for pertussis immunization in healthcare providers to prevent nosocomial transmission to infants and for maternal immunization in pregnant women for the prevention of pertussis in infants too young to be vaccinated (WHO recommendation). Boostagen$_{RED}^{TM}$ is not indicated for primary immunisation. • As per Indian SmPC "Tdapgen is indicated for active booster immunization against diphtheria, tetanus, and pertussis in individuals aged 4 to 65 years who have previously completed a primary vaccination series and require a booster dose. It is not to be used for the treatment of disease caused by B. pertussis, C. diphtheriae or C. tetani infection." • The firm has not submitted any details of doses administered in the country of origin or globally after the marketing authorization of the vaccine. In view of above and after detailed deliberation, the committee recommended that the firm should submit following information to the committee: 1. Post marketing data of the vaccine doses administered in the country

			of origin and globally. 2. Comparative safety and immunogenicity data of the vaccine in all age cohorts in the study conducted in Thailand vis-à-vis India. 3. Revised SmPC including India specific clinical trial data besides study conducted in the country of origin.
5.	Yellow Fever Vaccine (Live) (I.P) Phase III clinical trial protocol [BIO/CT/23/000002] (Re-deliberation)	M/s Serum Institute of India Pvt. Ltd.	In light of recommendation of SEC dated 05.02.2024, firm presented the two Phase III clinical trial reports conducted in children in other countries with request for grant of permission to conduct Phase III clinical trial in children in India for study titled, "A Phase III, Multicenter, Double blind, Randomized Study of SII Yellow Fever Vaccine to Compare Safety and Immunogenicity with STAMARIL® in Healthy children". The committee noted the safety and immunogenicity data of following clinical study reports: 1. A Phase III, Multicenter, Double blind, Randomized Study of SII Yellow Fever Vaccine to Compare Safety and Immunogenicity with STAMARIL® in Healthy Infants. (Study conducted in Mali and Gambia in participants of age group of 9 to < 12 months) 2. A Phase III, Multicenter, Double blind, Randomized Study of SII Yellow Fever Vaccine to Compare Safety and Immunogenicity with STAMARIL®. (Study conducted in Kenya in participants of age group of 1 to < 10 years, ≥ 10 to < 18 years and ≥ 18 years). 3. It was observed by the committee that although the non-inferiority criteria of the study conducted in Mali and Gambia in participants of age group of 9 to < 12 months) was not met, the vaccine showed SCR and SPR above 85 percent for the

			proposed vaccine. After detailed deliberation, the committee recommended to conduct the Phase III study in children as presented along with study in adults and the clinical trial sites should be notified to the concerned authority of the Yellow fever vaccination programme. [Dr Savita Verma did not participate in the deliberation]