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 28.07.2026 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 28.07.2026 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1.	Inactivated Hepatitis A Vaccine (Adsorbed) Phase II clinical trial protocol along with Phase I report BIO/CT/26/000011	M/s Biological E Limited	Firm presented Phase II clinical trial protocol titled, "A prospective, multicentre, randomized, open label, active controlled, Phase II study to evaluate safety and immunogenicity of two intramuscular doses of Biological E's inactivated Hepatitis A vaccine, administered 6 months apart, in ≥1- ≤50 years old healthy children, adolescents, and adults" along with Phase I clinical study report. After detailed deliberation, the committee noted the results of Phase I clinical study report and recommended for conduct of the Phase II clinical trial as per the presented protocol.
2	Varicella Vaccine (Live) I.P. (Freeze Dried) Phase III clinical trial protocol (Change in composition) BIO/CT/26/000060	M/s Zydus Lifesciences Limited	Firm presented Phase III clinical trial protocol titled, "A prospective, randomized, parallel, single-blind, two-arm, active-controlled, multicentre, phase III clinical trial to evaluate the immunogenicity and safety of Varicella Vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. compared to VARILRIX of M/s. GlaxoSmithKline Pharmaceuticals Ltd. in healthy pediatric participants aged 12 months to 12 years". The committee noted the following: - 1. Vaccine was already approved by CDSCO with different excipients. 2. Firm has proposed to conduct Phase III clinical trial due to change in excipients. 3. The blood sampling timepoints of 90 days for immunogenicity assessment should be revised to 270 days for long term immunogenicity assessment as exploratory endpoint. In view of above and after detailed

			deliberation, the committee recommended that the firm should submit revised protocol to CDSCO for further consideration.
3	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 20 valent New Drugs permission along with Phase-III Global clinical trial report (Additional indication) BIO/IMP/26/000067	M/s Pfizer Limited	Firm presented Phase III clinical trial report of global study titled, "A Phase 3, randomized, double-blind trial to evaluate the safety and immunogenicity of a 20-valent Pneumococcal conjugate vaccine given in a series of 3 infant doses and 1 toddler dose in infants in India and Taiwan". The committee noted that the firm presented modified safety and immunogenicity data by excluding results of one site due to absence of a biologically plausible explanation for immune responses between test and reference groups. In view of above and after detailed deliberation, the committee recommended that the firm should submit a protocol for conducting Phase III study in additional participants covering the intended age group of 6 weeks to less than 18 years in more than one site for further deliberation.
4	Measles and Rubella vaccine (Live) I.P. (Freeze Dried) Phase IV clinical trial report BIO/CT/24/000048 BIO/PostAppr/2026/46688	M/s Zydus Lifesciences Limited	Firm presented Phase IV clinical trial report titled, "A prospective, randomized, parallel, single-blind, four-arm, active-controlled, multicentre, phase IV clinical trial to evaluate the immunogenicity and safety of Measles and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. compared to Measles and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Serum Institute of India Pvt. Ltd. and to evaluate lotto-lot consistency of Measles and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. in healthy infants aged 9-12 months". After detailed deliberation, the committee noted the results.

5.	Rabies Vaccine, Human, I.P. Phase II clinical trial protocol along with Phase I report BIO/CT/26/000072	M/s Reliance Life Sciences Pvt Ltd	Firm presented Phase II clinical trial protocol titled, "A prospective, open label, randomized, comparative, phase II clinical trial to evaluate safety and immunogenicity of Purified vero cell Rabies Vaccine (PVRV) (Human) (R-VAC-002) of Reliance Life Sciences Pvt. Ltd. in comparison with Rabivax-S® of Serum Institute of India Pvt. Ltd, when administered as pre-exposure prophylaxis by Intramuscular or Intradermal Route in healthy adult human participants" along with Phase I clinical study report. After detailed deliberation, the committee recommended the following:- 1. Adequate number of female participants (at least 40%) should be included in the study. 2. Additional study site should be included besides the existing site. 3. The protocol should be revised w.r.t per protocol population, as those who have completed all three dose regime for immunogenicity evaluation. In view of above and after detailed deliberation, the committee noted the results of Phase I clinical study report and recommended that the firm should submit revised Phase II clinical trial protocol to CDSCO for further consideration.
6.	Recombinant, Influenza Vaccine (rIV) BIO/CT/26/000041 (Re-deliberation) Phase I/II clinical trial protocol	M/s Syngene International Limited	In light of recommendation of SEC dated 28.04.2026, firm presented revised Phase I/II clinical study protocol along with justification of dose selection for animal study. After detailed deliberation, the committee recommended that the firm should submit revised Phase I clinical trial protocol separating from Phase II protocol for further deliberation.