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 29.06.2026 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 29.06.2026 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1.	13 valent Pneumococcal Polysaccharide conjugate vaccine (TT/DT) Phase III Clinical Study Report [BIO/IMP/23/000076]	M/s NOVO Medi Sciences Private Limited	Firm presented Phase III clinical trial report titled, "A prospective, randomized, double-blind, multi-center, Phase III study to assess and compare the immunogenicity and safety of the 13-Valent Pneumococcal polysaccharide conjugate vaccine in healthy Indian subjects." After detailed deliberation, the committee noted the following: 1. The vaccine is approved in infants of 6 weeks to 5 years of age in country of origin i.e. China. 2. Firm presented immunogenicity and safety data generated in Indian healthy participants in comparison to reference vaccine in three cohorts (cohort 1: Adult 50 to 65 years, cohort 2: Adults & Adolescents & Children: 6 to less than 50 years and cohort 3: Infants 6 to 8 weeks). 3. The firm claimed numerically higher seroprotection rate for some specific serotypes of test vaccine in comparison to reference vaccine which should be revised in clinical study report as per approved protocol. 4. Comparative immunogenicity and safety data in Indian population with global population in the proposed age groups was not submitted. 5. Firm didn't present any immunogenicity data w.r.t concomitant vaccines administered in cohort 3, though it was mentioned in clinical study report. 6. Number of doses administered in China and other countries along with PMS data including PSUR data in all the proposed age groups were not presented.

			In view of above and after detailed deliberation, the committee recommended that firm should submit the above information for further deliberation.
2.	Inactivated Poliomyelitis Vaccine (Adsorbed) Phase III Clinical Study Report [BIO/MA/26/000057]	M/s Biological E. Limited	Firm presented Phase III clinical trial report titled, "A single blind, randomized, active-controlled, phase-III study to evaluate immunogenicity and safety of Biological E's inactivated poliomyelitis vaccine, administered to 6-8 weeks old healthy infants in 6-10-14 weeks dosing schedule". The committee noted the following: - (1) The firm presented interim clinical study report with immunogenicity and safety data upto day 84. However, complete study report containing 6 months safety data was not submitted as per approved protocol. (2) The firm presented immunogenicity data of three batches of vaccine to evaluate the lot-to-lot consistency and reported that the immune response of three batches were comparable for all three antigens. (3) The firm presented non-interference of test vaccine on co-administration with EPI vaccines and reported as non-inferior to comparator based on proportion of participants achieving seroprotection / seroconversion. After detailed deliberation, the committee recommended that the firm should submit the clinical study report along with complete safety data as per approved protocol for further deliberation.
3.	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP, 11-valent (Re-deliberation) [BIO/MA/25/000187]	M/s Panacea Biotec Limited	In light of the recommendation of SEC (Vaccine) dated 18.02.2026, the firm presented addendum to protocol dated 12.05.2026 incorporating the evaluation and regulatory consideration of the 3-dose (3+0) immunization schedule of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP, 11-valent for grant of new drug permission based on the interim analysis conducted after completion of the primary vaccination series. The committee noted that the firm has completed the three dose primary

			vaccination series and submitted the immunogenicity and safety data in the age group of 6, 10 and 14 weeks and has requested for new drug permission for 3+0 dose series. In view of above and after detailed deliberation, the committee recommended for grant of permission to manufacture Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) ,11-valent in the age group of 6, 10 and 14 weeks for primary vaccination (3+0) schedule.
4.	Typhoid Conjugate Vaccine (Bivalent) Phase III clinical trial protocol (Re-deliberation) [BIO/CT/25/000167]	M/s Serum Institute of India Pvt. Ltd.	In light of the recommendations of SEC (Vaccine) dated 22.12.2025, the firm presented the revised protocol. The committee noted the following: - 1) The firm changed the title to “A Phase 3 double-blind, randomized, active-controlled multicentric study to evaluate the safety and immunogenicity of a bivalent conjugate vaccine against Salmonella enterica serovars Typhi and Paratyphi A in healthy children aged 9 to 12 and 15 to 24 months” by excluding the term “Immune non-interference”. 2) The sample size of the study is not increased as per the recommendations of SEC (Vaccine) dated 22.12.2025. After detailed deliberation, the committee recommended to submit the revised protocol for further deliberation, retaining the title with immune non-interference with concomitant vaccination and including it as a primary objective, excluding the nomenclature superiority used in primary objective and appropriately increasing the sample size.