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 25.07.2025 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 25.07.2025 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1	Measles, Mumps, Rubella and Varicella vaccine Phase II/III Clinical trial protocol along with Phase I report. [BIO/CT/25/000048]	M/s. Zydus Lifesciences Ltd	The firm submitted application for grant of permission to conduct Phase II/III clinical trial along with Phase I study report. The firm presented the Phase II/III protocol titled, "A prospective, randomized, parallel, single-blind, two arm, active-controlled, multicentre, phase II/III clinical trial to evaluate the immunogenicity and safety of Measles, Mumps, Rubella and Varicella vaccine of M/s. Zydus Lifesciences Ltd. compared with Measles, Mumps, Rubella and Varicella vaccine of M/s. GlaxoSmithKline Biologicals in healthy children aged 15-18 months. The committee noted that Phase I clinical trial permission was granted in 2015 and the clinical study report is submitted recently in 2025 and also the firm has proposed new formulation of Varicella Vaccine in the applied product. Therefore, the committee opined that applicant is required to clarify the following points: - 1. Justification for the delay in the submission of Phase I study report. 2. Differences in the vaccine formulation used in Phase I and proposed in Phase II/III protocol with respect to inactive ingredients & manufacturing process and justification for consideration of the Phase I report for conduct of Phase II / III study.

			3. Justification for proposing Phase II/III clinical trial in the age group 15 – 18 months with new formulation and not proposing a Phase I protocol in healthy adult population with new formulation. 4. Justification for the limited sample size in Phase II/III study with new formulation. 5. Non-inferiority is not incorporated as primary objective in currently proposed Phase II/III clinical trial protocol. In view of above and after detailed deliberation, the committee recommended that the firm should submit adequate response with justification along with Phase I clinical trial protocol in healthy adult subjects with proposed new formulation for further review by the committee.
2	Combined Tetanus Toxoid, Reduced Diphtheria Toxoid, Reduced Recombinant Pertussis vaccine (Tdapgen) MA with Phase III study report [BIO/IMP/25/000063]	M/s Techinvention Lifecare Ltd.	The firm submitted application to import Combined Tetanus Toxoid, Reduced Diphtheria Toxoid, Reduced Recombinant Pertussis vaccine ($Tdap_{gen}$) for sale or for distribution along with report of Phase III clinical trial conducted in India. The firm presented the Phase III study report titled “A multicenter, randomized, observer-blind, non-inferiority, Phase III study to evaluate the immunogenicity and Safety of $Boostagen_{RED}^{TM}$ (combined tetanus toxoid, reduced diphtheria toxoid, reduced recombinant pertussis vaccine) by BioNet-Asia compared to ADACEL® vaccine by Sanofi Pasteur Limited in healthy subjects aged 4-65 years”.

			The committee noted the following points: - 1. Firm has not submitted the clinical study report with (a) Age stratification as proposed in the Phase III clinical trial protocol with three groups (Group 1: 18-65 years; Group 2: 10-17 years; Group 3: 4-9 years) with respect to primary and secondary endpoints. (b) Three seroconversion criteria as per approved protocol but has submitted the report with only one criteria (as more than equal to 4-fold rise in post vaccination antibody concentration relative to pre-vaccination concentration). 2. The proposed product is combined Tetanus Toxoid, Reduced Diphtheria Toxoid, Reduced Recombinant Pertussis vaccine ($Tdap_{gen}$) with reduced recombinant Pertussis Toxoid for which the firm is required to furnish regulatory status and total number of doses used in the country of origin and globally. 3. Indication in the Phase III clinical trial protocol including the inclusion criteria is different from the currently submitted clinical study report and new drug application. 4. Approved prescribing information in the country of origin with respect to the applied vaccine with reduced recombinant Pertussis Toxoid. 5. Baseline titer as well as cut-off post vaccination antibody concentration of anti-PT and anti-FHA is not defined.

			In view of above and after detailed deliberation, the committee recommended that the firm should submit adequate response with justification for further review by the committee.
3.	Quadrivalent Influenza Vaccine + Litevax Adjuvant (TETRALITE) Phase I Clinical Trial Protocol (Re-deliberation) [BIO/CT/24/000157]	M/s.Translational Health Science and Technology Institute, Ministry of Science and Technology, Govt. of India, Faridabad, India.	In light of the recommendations of SEC (Vaccine) on 15.01.2025, the firm submitted the additional information as below: - 1. Vaccine preparation protocol (VPP) version no. 1.0 dated 13.05.2025 with detailed composition of the reconstituted vaccine, procedure of reconstitution, handling, storage, transportation and administration of reconstituted vaccine which includes adjuvant and saline. In-use stability data of the reconstituted vaccine was submitted along with stability report of the drug product. 2. Phase Ia report and updated status of Phase Ib trial conducted in Europe. 3. Additional preclinical safety study results. The committee noted the Phase Ia study report and the updated status of Phase Ib study report conducted in Europe. After detailed deliberation, the committee recommended for conduct of Phase I study as per protocol submitted by the firm.
4.	Cemdisiran 200 mg/ml liquid formulation for Subcutaneous administration +	M/s.Parexel International Clinical Research Private	The firm presented the justification for the import of Meningococcal Serotype B

	Pozelimab 200 mg/ml liquid formulation for SC administration Phase III clinical trial protocol amendment [GCT/PostAppr/2025/35679]	Limited	vaccine as per amended protocol as additional safety measures to reduce the risk of serious infections in the participants of the already approved clinical trial. After detailed deliberation, the committee recommended for the import of the Meningococcal Serotype B vaccine only for the use in the clinical trial participants as proposed.
5.	Cemdisiran 200 mg/ml liquid formulation for Subcutaneous administration + Pozelimab 200 mg/ml liquid formulation for SC administration Phase III clinical trial protocol amendment [GCT/PostAppr/2025/34689]	M/s. Parexel International Clinical Research Private Limited	The firm presented the justification for the import of Meningococcal Serotype B vaccine as per amended protocol as additional safety measures to reduce the risk of serious infections in the participants of the already approved clinical trial. After detailed deliberation, the committee recommended for the import of the Meningococcal Serotype B vaccine only for the use in the clinical trial participants as proposed.