

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 18.02.2026 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 18.02.2026 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1.	Recombinant Rabies G Protein Vaccine 50 mcg/0.5 ml Phase III Clinical Trial Protocol [BIO/CT/25/000201]	M/s Cadila Pharmaceuticals Limited	<p>The firm submitted the clinical study report with reference to the permission issued by this office for conduct of Phase III clinical trial of THRABIS vaccine (Recombinant Rabies G Protein Vaccine) wherein the primary and secondary endpoints were found to be inconclusive although the vaccine met the safety endpoint.</p> <p>In light of above, the firm submitted and presented revised Phase III clinical trial protocol titled, "A randomized, open-label, assessor blind, parallel, active-controlled, multicentric, bridging clinical trial to evaluate the immunogenicity and safety of three dose THRABIS vaccine (Recombinant Rabies G Protein Vaccine), administered as a simulated post-exposure immunization in healthy children".</p> <p>After detailed deliberation, the committee recommended for conduct of the Phase III clinical trial with the condition that the firm should revise the protocol as below: -</p> <ol style="list-style-type: none"> (1) the primary objective and primary end point should mention seroprotection rate attained on 14th day after first dose of vaccine. (2) ensure representation from all age groups (1 to 6 years, 7 to 12 years and 13 to 18 years) in the study with blood samples withdrawal as below: 5 ml each at screening day and day 42, 2.5 ml each at day 0 and day 14 for both safety and immunogenicity endpoints. (3) mentioning screening day as -7 to -1 (4) defining non-inferiority criteria under statistical method of the protocol and applying 10% margin at 5% alpha and 90% power with respect to test vaccine based on Phase III study results in adults. (5) to remove "pregnant and lactating girls as well as female subjects of

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 18.02.2026 (through hybrid mode)

			<p>child bearing age not using acceptable contraceptive measures” from exclusion criteria.</p> <p>(6) the clinical trial sites should be geographically distributed across the country.</p> <p>Accordingly, firm should submit revised protocol to CDSCO for further review.</p>
2.	<p>DTwP-HepB-IPV-Hib (Liquid Hexavalent Vaccine)</p> <p>Phase III CT report for New drug Permission</p> <p>(Re-deliberation) [BIO/MA/25/000159]</p>	M/s. Biological E Ltd.	<p>In light of recommendation of SEC dated 22.12.2025, firm submitted and presented demographic data and DSMB recommendations in detail.</p> <p>After detailed deliberation, the committee noted the data & results presented by the firm and recommended for grant of new drug permission.</p> <p>(Dr. Savita Verma did not participate in deliberation)</p>
3.	<p>Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) (2+1 dosing schedule)</p> <p>Phase III CT report for Marketing Authorization (Additional Indication)</p> <p>(Re-deliberation) [BIO/MA/25/000121]</p>	M/s. Biological E Ltd.	<p>In light of recommendation of SEC dated 24.09.2025, firm submitted the following: -</p> <ol style="list-style-type: none"> 1. Causality analysis of the adverse events with case diagnosis where concomitant medications which were given to participants during the study period. 2. Comparative safety and immunogenicity data of 3+0 study v/s 2+1 study as per serostatus at baseline. <p>After detailed deliberation, the committee noted the results of Phase III study and recommended the additional indication of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) for 2+1 alternative dosing schedule.</p>
4.	<p>Hexavalent Vaccine [Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis-B (rDNA), Reduced Poliomyelitis (Inactivated) and Haemophilus influenzae type b Conjugate Vaccine (Adsorbed)]</p> <p>Phase III clinical trial report for New drugs permission</p>	M/s Serum Institute of India Pvt. Ltd.	<p>Firm presented Phase III clinical trial report titled “An observer-blind, randomized, active-controlled, multicentric Phase III study in infants and toddlers to assess the immunogenicity and safety of SIIPL HEXAVALENT (DTwP-Hep-B-IPV-Hib) Vaccine containing reduced dose IPV in comparison with SIIPL HEXASIIIL®”.</p> <p>The committee noted the following: -</p> <ol style="list-style-type: none"> 1. clinical study report is presented with combined outcome of primary and

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 18.02.2026 (through hybrid mode)

	[BIO/MA/26/000001]		<p>secondary endpoints of Indian and Bangladesh population.</p> <ol style="list-style-type: none"> the firm presented clinical study report with the results of three dose regimen (6, 10 & 14 weeks) for primary vaccination. the firm would complete the booster dose at the age of 12 to 24 months and would assess and compare the pre- and post-booster immunogenicity of SIIPL reduced IPV HEXAVALENT vaccine with the comparator vaccine viz., SIIPL HEXASIIIL® as an exploratory endpoint. <p>After detailed deliberation, the committee recommended that the firm should submit the complete Phase III study report with primary, secondary and exploratory endpoints specific to Indian population for further deliberation.</p>
5.	<p>Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed), 11 valent</p> <p>Phase II/III clinical trial report (Interim report: Primary immunization phase) for New drugs permission</p> <p>[BIO/MA/25/000187]</p>	M/s Panacea Biotec Ltd.	<p>Firm presented Phase II/III clinical trial interim report titled "A randomized, open label, multicenter, Phase II / III study to assess and compare the immunogenicity and safety of NUCOVAC®-11 {Pneumococcal Polysaccharide conjugate vaccine (Adsorbed), 11 valent} of Panacea Biotec Ltd. with PREVENAR 13® of Pfizer Inc. in healthy infants (3+1 Immunization Schedule)".</p> <p>The committee noted the following: -</p> <ol style="list-style-type: none"> firm presented the interim study report with primary endpoint data. the study is on-going for the secondary objectives which includes booster administration at 15 to 18 months of age and monitoring of safety & reactogenicity throughout the study period. <p>After detailed deliberation, the committee recommended to submit the complete Phase III clinical study report after completion of the study as per approved protocol for further deliberation.</p>