

**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 28.05.2026 (through hybrid mode)**

**The Recommendations:**

The SEC (Vaccine) deliberated the proposals on 28.05.2026 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1.	<p>Mycobacterium Tuberculosis (Live, Attenuated) Vaccine</p> <p>Phase III Clinical Trial Protocol along with Interim Phase II Clinical Study Report</p> <p>[BIO/CT/26/000059]</p>	<p>M/s Bharat Biotech International Limited</p>	<p>The firm presented the Phase III clinical trial protocol titled, "A Phase III, randomized, double-blind, placebo-controlled, multicentre clinical trial to evaluate the efficacy, safety, and immunogenicity of MTBVAC (BBV169), a Live Attenuated Mycobacterium tuberculosis Vaccine, for the prevention of tuberculosis disease in Indian adolescents and adults along with interim Phase II clinical study report.</p> <p>The Committee noted the following:</p> <ol style="list-style-type: none"> <li>1. Firm has submitted Phase II interim clinical study report with 90 days safety and 56 days immunogenicity data as per approved protocol.</li> <li>2. Interim immunogenicity analyses through Day 56, demonstrated comparable immunogenicity to BCG in both QFT-negative and QFT-positive participants.</li> <li>3. However, Immunogenicity data of MTBVAC at Day 0, 28 and 56 need to be submitted for reconfirmation of outcome of primary objective of Phase II studies.</li> <li>4. Age stratified data for adolescents and adults have not been submitted as per approved protocol.</li> <li>5. Graphical presentation of Cell Mediated Response and Responder Rates of Phase I Immunogenicity data need to be reverified and presented with the raw data of all subjects.</li> <li>6. Genomic analysis of SAE case to be carried out to distinguish between wild strain versus vaccine induced strain.</li> </ol> <p>In view of above and after detailed deliberation, the committee recommended that the firm should submit above information along with revised Phase III protocol incorporating the various suggestions of the committee with respect to primary endpoints, administration of IP in</p>

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			<p>the double-blind design, immunogenicity cohort, statistical design for determination of efficacy outcome for further deliberation.</p> <p>(Dr. Savita Verma did not participate in deliberation)</p>
2.	<p>Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent)</p> <p>Additional Indication for (3+1 Alternative Dosing Schedule)</p> <p>[BIO/MA/26/000008]</p>	M/s Biological E. Limited	<p>Firm presented Phase IV clinical trial report titled, "A prospective multicenter Phase-IV study to evaluate the safety of Biological E's 14-valent pneumococcal polysaccharide conjugate vaccine when administered in 6-10-14 weeks dosing schedule to 6-8 weeks old healthy Indian infants.</p> <p>After detailed deliberation, the committee noted the results of Phase IV study.</p> <p>(Dr. Savita Verma did not participate in deliberation)</p>
3.	<p>Quadrivalent Human Papillomavirus (Serotypes 6, 11, 16 &amp; 18 Vaccine) (Adsorbed)</p> <p>Phase IV Clinical Trial Report</p> <p>[BIO/CT/23/000055]</p> <p>[BIO/PostAppr/2026/45262]</p>	M/s Serum Institute of India Pvt. Ltd.	<p>Firm presented Phase IV clinical trial report titled, "A Phase-IV, single-arm, multicentric study to assess the safety of SIIPL's qHPV vaccine when administered in a two-dose schedule to girls and boys aged 9-14 years and in a three-dose schedule to women and men aged 15-26 years."</p> <p>After detailed deliberation, the committee noted the results of Phase IV study.</p> <p>(Dr. Savita Verma did not participate in deliberation)</p>
4.	<p>Measles, Mumps and Rubella vaccine (Live) I.P.</p> <p>Update to the India Prescribing Information (PI)</p> <p>[BIO/PostAppr/VAC/2025/2869]</p>	M/s GlaxoSmithKline Pharmaceuticals Limited (GSK)	<p>Firm presented its proposal for updation of prescribing information for Measles, Mumps and Rubella vaccine (Live) I.P. for following: -</p> <ol style="list-style-type: none"> <li>1) Update of Congenital Rubella Syndrome case under Pregnancy and Lactation section.</li> <li>2) Addition of immunosuppressive therapy (including high dose corticosteroids) as a Contraindication and related update under Warnings and Precautions section.</li> </ol> <p>After detailed deliberation, the committee recommended for the updation in the PI aligned with EU SmPC.</p>

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5.	<p>Measles, Mumps, Rubella and varicella vaccine (Live) Ph. Eur.</p> <p>Update to the India Prescribing Information (PI)</p> <p>[BIO/PostAppr/VAC/2026/3290]</p>	<p>M/s GlaxoSmithKline Pharmaceuticals Limited (GSK)</p>	<p>Firm presented its proposal for updation of prescribing information for Measles, Mumps Rubella and Varicella vaccine (Live) I.P. for following: -</p> <ol style="list-style-type: none"> <li>1. Clarification on immunosuppressive therapy (including high dose corticosteroids) under contraindication and Special Warnings and Precautions for use sections.</li> <li>2. Update of information on encephalitis under Special Warnings and Precautions for Use section.</li> <li>3. Update of Congenital Rubella Syndrome case under Pregnancy and Lactation section.</li> <li>4. Update of clarification on clinical studies and additional information on encephalitis under Undesirable Effects section.</li> </ol> <p>After detailed deliberation, the committee recommended for the updation in the PI aligned with EU SmPC.</p>
6.	<p>Varicella Vaccine, Live I.P.</p> <p>Update to the India Prescribing Information (PI)</p> <p>[BIO/PostAppr/VAC/2026/3489]</p>	<p>M/s GlaxoSmithKline Pharmaceuticals Limited (GSK)</p>	<p>Firm presented its proposal for updation of prescribing information for Varicella Vaccine, Live I.P for following: -</p> <ol style="list-style-type: none"> <li>1) Clarification on immunosuppressive therapy (including high dose corticosteroids) under contraindication and Special Warnings and Precautions for use sections.</li> <li>2) Update of information on encephalitis under Special Warnings and Precautions for Use section</li> <li>3) Update of additional information on encephalitis under Undesirable Effects section.</li> </ol> <p>After detailed deliberation, the committee recommended for the updation in the PI aligned with EU SmPC.</p>