

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 03.10.2024 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 03.10.2024 and recommended the following:

Sr. No.	Name of Vaccine & File no.	Name of Firm	Recommendations
1	<p>Rabies Human Monoclonal Antibody (Rabishield) and Rabivax-S</p> <p>[Phase IV Clinical Trial Report]</p> <p>[BIO/CT/18/000091 (BIO/PostAppr/2024/33442)]</p>	<p>M/s Serum Institute of India Pvt. Ltd., Pune</p>	<p>The firm presented the Phase IV clinical trial report titled “A Phase IV, Randomized, Controlled Study of Safety and Immunogenicity of Rabishield + Rabivax-S Post-Exposure Prophylaxis regimen in Patients with Potential Rabies Exposure.”</p> <p>After detailed deliberation, the committee noted the results of the study.</p>
2	<p>Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze-Dried)</p> <p>[Phase-IV Clinical Trial Protocol]</p> <p>[BIO/CT/24/000018]</p>	<p>M/s Serum Institute of India Pvt. Ltd., Pune</p>	<p>In light of the recommendation of SEC (vaccine) meeting dated 27.03.2024, the firm presented the revised Phase IV clinical trial protocol titled, “A Phase IV, double blind, randomized, active control clinical study comparing safety and immunogenicity of SII-Measles-Mumps- Rubella vaccine with PRIORIX (GSK) in healthy infants in India.”</p> <p>After detailed deliberation, the committee recommended for approval of Phase IV clinical trial protocol as presented with condition of inclusion of site from eastern part of India.</p>
3	<p>Recombinant Hepatitis E Vaccine (E. Coli)</p> <p>[Phase-IV Clinical Trial Protocol]</p> <p>[BIO/CT/24/000101]</p>	<p>M/s Urihk Pharmaceutical Private Limited, Mumbai</p>	<p>The firm presented the Phase IV clinical trial protocol titled, “A prospective, multicentre, single arm, Phase IV study to evaluate the safety and immunogenicity of Recombinant Hepatitis E Vaccine (E. Coli) in Healthy Adults.”</p>

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			<p>After detailed deliberation, the committee recommended for approval of Phase IV clinical trial protocol as presented with the following conditions: -</p> <ol style="list-style-type: none"> 1. The firm should include safety and immunogenicity as the primary end points as per the recommendations of SEC dated 30.04.2024. 2. The firm should demonstrate safety and seroconversion with age and gender stratification (18 to 35, 36 to 50 and 51 to 65 years) as secondary end point. <p>Accordingly, the firm should submit revised protocol to CDSCO.</p>
4	<p>Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14-valent)</p> <p>[Phase-IV Clinical Trial Protocol]</p> <p>[BIO/CT/24/000082]</p>	<p>M/s Biological E. Limited, Hyderabad</p>	<p>The firm presented the Phase IV clinical trial protocol titled, "A single blind, randomized, active-controlled, Phase IV study to evaluate immunogenicity and safety of Biological E's 14-valent Pneumococcal Polysaccharide Conjugate Vaccine (PNEUBEVAX-14), administered to healthy children aged ≥5 years to <18 years and healthy adults aged ≥18 years and above."</p> <p>After detailed deliberation, the committee recommended for approval of Phase IV clinical trial protocol as presented.</p> <p>(Dr Savita Verma didn't participated in the deliberation)</p>

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5	<p>Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14-valent) [PCV-14]</p> <p>[Phase-IV Clinical Trial Protocol (amendment)]</p> <p>[BIO/CT/23/000065 (BIO/PostAppr/2024/33618)]</p>	<p>M/s Biological E. Limited, Hyderabad</p>	<p>In light of the recommendation of SEC dated 31.07.2024, the firm presented the amended Phase IV clinical trial protocol titled "A prospective multicentre Phase-IV study to evaluate the safety of Biological E's 14-valent Pneumococcal Polysaccharide Conjugate Vaccine (PNEUBEVAX-14) when administered in 6-10-14 weeks dosing schedule to 6-8 weeks old healthy Indian infants."</p> <p>After detailed deliberation, the committee recommended for approval of Phase IV clinical trial protocol as presented.</p> <p>(Dr Savita Verma didn't participated in the deliberation)</p>
6	<p>Diphtheria and Tetanus (Td) Vaccine (Adsorbed) [Phase-II/III Clinical Trial Report] [MA] [BIO/MA/24/000094]</p>	<p>M/s Panacea Biotec Ltd., New Delhi</p>	<p>Firm presented the proposal for grant of permission to manufacture Diphtheria and Tetanus (Td) Vaccine (adsorbed) along with clinical trial report of Phase II/ III clinical trial conducted in the country.</p> <p>After detailed deliberation, the committee noted the results of Phase II/III clinical trial and recommended for the grant of manufacturing permission of Diphtheria and Tetanus (Td) Vaccine (Adsorbed).</p>
7	<p>Measles and Rubella Vaccine (Live) I.P. (Freeze Dried) [MA] [BIO/MA/24/000075]</p>	<p>M/s Zydus Lifesciences Limited, Ahmedabad</p>	<p>The firm presented the amendment in manufacturing permission of Measles and Rubella Vaccine (live) I.P. (freeze dried) - multi dose vial (5 ml-10</p>

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			<p>dose) due to change in composition of vaccine with respect to quantities of inactive ingredients due to change in fill volume.</p> <p>After detailed deliberation, the committee recommended for approval of amendment in manufacturing permission for change in composition of vaccine with respect to quantities of inactive ingredients subject to recommendations from CDL, Kasauli.</p>
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