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 28.08.2025 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 28.08.2025 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1	Inactivated Chikungunya vaccine Phase II report of Phase II / III Study [BIO/CT/20/000137] [BIO/PostAppr/2025/39779]	M/s Bharat Biotech International Ltd.,	The firm presented Phase II report of the study titled, "A Seamless Phase II / III, observer blind, multi-centre, randomized Clinical trial to evaluate immunogenicity and safety of BBV87, an Inactivated Chikungunya Virus Vaccine in healthy subjects 12-65 years of age". After detailed deliberation, the committee noted the results of Phase II trial and recommended for the conduct of Phase III trial as per presented protocol. (Dr. Savita Verma did not participate in the deliberation)
2	Dengue tetravalent vaccine (live, attenuated) MA with India specific blinded interim safety study analysis report of the ongoing Phase III clinical trial (DEN-302) [BIO/IMP/24/000037]	M/s Takeda Biopharmaceuticals India Pvt. Ltd., Gurgaon	The firm presented India specific blinded interim safety analysis report of the ongoing Phase III clinical trial titled, "A randomized, double-blind, placebo-controlled, Phase III trial to investigate the safety and immunogenicity of a Dengue Tetravalent Vaccine (live, attenuated) (TDV) administered subcutaneously to healthy subjects aged 4 to 60 years in India". After detailed deliberation, the committee recommended that the firm should submit complete Phase III clinical trial report after completion of the on-going study in Indian population for further deliberation.
3.	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B(rDNA) and Haemophilus influenza Type b Conjugate vaccine (Adsorbed), IP	M/s Panacea Biotec Ltd., New Delhi	The firm presented Phase I clinical trial protocol titled, "An open label, non-comparative, Phase I study to evaluate the safety, tolerability and preliminary immunogenicity of a

	Phase - I clinical trial protocol [BIO/CT/25/000063]		fully liquid pentavalent DTwP-HepB-Hib vaccine (MyFive™, Panacea Biotec Ltd.) in healthy subjects 15 - 18 months of age". After detailed deliberation, the committee recommended for the conduct of Phase I trial as per presented protocol.
4.	13- Valent Pneumococcal Polysaccharide Conjugate Vaccine Amendment in approved Phase III Clinical trial Protocol for Booster dose administration in infants. [BIO/PostAppr/2025/37122] [BIO/CT/23/000101]	M/s Novo Medi Sciences Private Limited	The firm presented revised Phase III clinical trial Protocol for booster dose administration in infants 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 recommended for the conduct of the study as per presented protocol.
5.	Diphtheria, Tetanus, Pertussis (Acellular Component), Hepatitis B (r-DNA), Poliomyelitis (Inactivated) and Haemophilus Influenzae Type B Conjugate Vaccine (Adsorbed)I.P. Updation of prescribing information (PI) (CCDSv11 dated 14th Oct 2021 (LRR13886). [BIO/PostAppr/Vac/2024/914] [12-36/SANOFI/15-BD]	M/s Sanofi Healthcare India Private Limited	Firm presented its proposal for updation of prescribing information (PI) (CCDSv11 dated 14th Oct 2021 (LRR13886). After detailed deliberation, the committee recommended for updation in line with EU SmPC. Further, the firm should monitor the interaction of the vaccine with Varicella containing vaccines in Indian population and submit the same as part of PSUR submission.