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 22.05.2025 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 22.05.2025 and recommended the following:

Sr. No.	Name of Vaccine & File no.	Name of Firm	Recommendations
1	Tetanus Vaccine (Adsorbed). I.P Phase III Clinical Trial Protocol (SEC Re-deliberation) [BIO/CT/23/000129]	M/s Indian Immunologicals Limited, Hyderabad	In light of SEC recommendation dated 05.02.2024, the firm presented the following:- 1.Developmental and Reproductive Toxicity (DART) study reports in rats and rabbits. 2. Post Marketing safety data on the marketed vaccine. 3. Published report After detailed deliberation, the committee recommended for conduct of the Phase III clinical trial in healthy pregnant women as per the protocol submitted.
2	Diphtheria and Tetanus Vaccine (Adsorbed) I.P Phase III Clinical Trial Protocol (SEC Re-deliberation) [BIO/CT/23/000154]	M/s Indian Immunologicals Limited, Hyderabad	In light of SEC recommendation dated 05.02.2024, the firm presented the following:- 1.Developmental and Reproductive Toxicity (DART) study reports in rats and rabbits. 2. Post Marketing safety data on the marketed vaccine. After detailed deliberation, the committee recommended for conduct of the Phase III clinical trial in healthy pregnant women as per the protocol submitted.

3.	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (21 valent) Phase 1 Clinical Trial Protocol [BIO/CT/25/000043]	M/s Serum Institute of India Pvt. Ltd	The firm presented Phase I clinical trial protocol, titled "A Phase 1, prospective, randomized, two-arm, active-controlled, double-blind study to evaluate the safety, tolerability and immunogenicity of Serum Institute of India's 21-valent Pneumococcal Conjugate Vaccine (SIIPCV21) in Healthy Indian Adults". After detailed deliberation, the committee recommended for conduct of the Phase I clinical trial as per the presented protocol.
4.	Inactivated Salk Polio Vaccine (Adsorbed) [MA] [BIO/MA/25/000049]	M/s Serum Institute of India Pvt. Ltd	The firm presented Phase II/III clinical trial report, "A Phase II/III, multicenter, double-blind, randomized, active controlled study to evaluate safety and immunogenicity of SII Inactivated Salk Polio Vaccine (Adsorbed) in comparison with SII Licensed Inactivated Poliovirus Vaccine (IPV)" for manufacturing and marketing permission of Inactivated Salk Polio Vaccine (Adsorbed). After detailed deliberation, the committee noted the results of the clinical study report and recommended for grant of manufacturing and marketing permission of Inactivated Salk Polio Vaccine (Adsorbed).
5.	BCG Vaccine (Freeze Dried) I.P PMS Study Protocol VAC- 11012(11)/1/2025-eoffice (E.No 22852)	M/s Green Signal Bio Pharma Pvt Ltd.	The firm presented the post marketing surveillance study titled "An open label, prospective, multicentre, single arm, single treatment, single dose post marketing surveillance study to evaluate the safety and tolerability of BCG Vaccine (freeze - dried) IP of M/s. Green Signal Bio Pharma Private Limited, Chennai, India".

			After detailed deliberation, the committee recommended to submit revised protocol with following changes for further deliberation: (1) Firm should revise the inclusion criteria to include only those individuals who have not received BCG vaccine previously. (2) Sample size should be specified in two cohorts - less than 1 year and greater than or equal to 1 year. (3) Population for skin tuberculin test to be clearly specified.
6.	Typhoid Vi Conjugate Vaccine (Typhoid (Vi Capsular Polysaccharide) Tetanus Toxoid Conjugate Vaccine) Phase III Clinical Trial Report [BIO/CT/23/000112] [BIO/PostAppr/2025/38061]	M/s Bharat Biotech International Limited	The firm presented Phase III clinical trial report titled “A Phase III open-label study to evaluate the immunogenicity and safety of Typhoid Tetanus Toxoid conjugate vaccine; Typbar TCV® in adults (>65 Years)”. After detailed deliberation, the committee noted the results of the Phase III clinical study.
7.	Inactivated Influenza Vaccine (Split Virion) I.P [PI Update] BIO/PostAppr/VAC/2025/1892	M/s GSK Pharmaceuticals Limited	Firm presented its proposal for updation of prescribing information of Inactivated Influenza Vaccine (Split Virion) I.P. in alignment with EU SmPC. After detailed deliberation, the committee recommended for the updation in the PI aligned with EU SmPC.