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 15.01.2025 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 15.01.2025 and recommended the following:

Sr. No.	Name of Vaccine & File no.	Name of Firm	Recommendations
1	Meningococcal Group A, C, W-135, Y, X Conjugate Vaccine (Adsorbed & Un-adsorbed). [Phase-I CT Protocol] [BIO/CT/24/000140]	M/s Biological E. Limited, Hyderabad	The firm presented Phase I clinical trial protocol titled, "A prospective, open label, randomized, controlled Phase I clinical study to evaluate the safety and immunogenicity of single intramuscular dose of Biological E's Meningococcal Conjugate Vaccine, administered to 18-45 years old healthy adults." After detailed deliberation, the committee recommended for conduct of the Phase I clinical trial as per the presented protocol.
2	Inactivated Poliomyelitis Vaccine (Adsorbed) [Phase II study report along with Phase III CT Protocol] [BIO/CT/24/000158]	M/s Biological E. Limited, Hyderabad	The firm presented Phase II study report along with Phase III clinical trial Protocol, titled, "A single blind, randomized, active-controlled, Phase III study to evaluate immunogenicity and safety of Biological E's inactivated poliomyelitis vaccine, administered to 6-8 weeks old healthy infants in 6-10-14 weeks dosing schedule." The committee noted the results from Phase II clinical trial report. After detailed deliberation, the committee

			recommended for conduct of the Phase III clinical trial as per the presented protocol. (Dr. Savita Verma didn't participate in deliberation)
3.	Hepatitis A (Live) Vaccine, Freeze-Dried Injection [CT Phase III Report (Re-deliberation)] [BIO/IMP/24/000049]	M/s Joint Force Pharmachem Pvt. Ltd., Mumbai	In light of the recommendation of SEC (Vaccine) meeting dated 22.08.2024, the firm presented the additional data of the Phase III results for grant of permission to import Freeze-dried Live Attenuated Hepatitis A Vaccine. After detailed deliberation, the committee noted the results of the additional data along with the Phase III clinical trial report and recommended for grant of permission to import Hepatitis A (Live) Vaccine, Freeze-Dried Injection with condition to conduct Phase IV clinical trial with safety and immunogenicity as primary endpoints on at least 1000 subjects. The protocol for Phase IV clinical trial should be submitted to CDSCO within 2 months and data from this trial should be submitted forthwith for continuing the import and marketing permission.
4.	Quadrivalent Influenza Vaccine + Litevax Adjuvant (TETRA^{LITE}) [Phase I CT Protocol]	Translational Health Science and Technology Institute, Faridabad.	The applicant has presented Phase I clinical trial protocol titled, "A randomized, Phase I, single-centre, observer-blind, active-controlled, 3-arm

	[BIO/CT/24/000157]		study to evaluate the safety, tolerability, and immunogenicity of a single administration of TETRA^{LITE}, a novel adjuvanted influenza vaccine, in healthy participants aged 18 to 50 years." After detailed deliberation, the applicant was requested to submit the following information for further deliberation :- 1. Pharmacy Manual with detailed composition and stability data of the reconstituted vaccine, procedure of reconstitution, handling, storage, transportation and administration of reconstituted vaccine which includes adjuvant and saline. 2. Phase Ia report and updated status of Phase Ib trial conducted in Europe. 3. Additional clarification on pre-clinical safety study results.
5.	Influenza Vaccine (Human, Live Attenuated) I. P., Trivalent [MA with CT waiver] [BIO/MA/24/000140]	M/s Serum Institute of India Pvt. Ltd.	Firm presented its proposal for grant of manufacturing and marketing permission for Influenza vaccine (Human, Live Attenuated) (Liquid), Seasonal, Trivalent (Intranasal), with a request for clinical trial waiver. The committee noted that the firm is already holding manufacturing and

			marketing permission for Influenza vaccine (Human, Live Attenuated) (Liquid), Seasonal, Quadrivalent (Intranasal) and now, firm has submitted the current proposal based on WHO's recommendation dated 29.09.2023 for switching from Quadrivalent to liquid trivalent Influenza vaccine (Intranasal). After detailed deliberation and in view of above, the committee recommended for grant of manufacturing and marketing permission of Influenza vaccine (Human, Live Attenuated) (Liquid), Seasonal, Trivalent (Intranasal).
6.	MTBVAC [Amendment in Phase II CT protocol] [BIO/CT/24/000042 & BIO/PostAppr/2024/36090]	M/s Bharat biotech International Pvt. Ltd.	The firm presented amendment in Phase II clinical trial protocol titled, "A Phase II Randomized, Double-blind Trial to Access the Safety and Immunogenicity of MTBVAC (BBV169), with BCG vaccine as a comparator in Healthy adolescent and adult populations" After detailed deliberation, the committee recommended for approval of amended Phase II clinical trial protocol as presented by the firm.