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 26.03.2025 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 26.03.2025 and recommended the following:

Sr. No.	Name of Vaccine & File no.	Name of Firm	Recommendations
1	Typhoid Vi Conjugate Vaccine I.P. [Phase-IV CT protocol] [BIO/CT/25/000009]	M/s. Zydus Lifesciences Ltd.	The firm presented Phase IV clinical trial protocol titled, "A prospective, parallel, open-label, two-arm, multicentre, Phase IV clinical trial to evaluate the immunogenicity and safety of Typhoid Vi Conjugate Vaccine I.P. of M/s. Zydus Lifesciences Ltd. in malnourished children as compared to healthy children". After detailed deliberation, the committee recommended for conduct of the Phase IV clinical trial as per the presented protocol with condition to include sites from states of Rajasthan, Bihar and Madhya Pradesh also.
2	Bivalent Typhoid and Paratyphoid A Conjugate Vaccine. [Phase II CT protocol along with Phase I report] [BIO/CT/25/000010]	M/s. Zydus Lifesciences Ltd.	The firm presented Phase I clinical trial report along with Phase II clinical trial protocol titled "A prospective, randomized, parallel, single-blind, two-arm, active-controlled, multicenter, age de-escalation, Phase II clinical trial to evaluate the immunogenicity and safety of Bivalent Typhoid and Paratyphoid A Conjugate Vaccine of M/s. Zydus Lifesciences Ltd. as compared to Typhoid Vi Conjugate Vaccine of M/s. Zydus Lifesciences Ltd. in healthy participants". The committee noted the results of Phase I clinical trial. After detailed deliberation, the committee recommended for conduct of the Phase II clinical trial

			as per the presented protocol.
3.	Typhoid and Paratyphoid A Bivalent Vaccine. [Phase I CT Protocol] [BIO/CT/24/000036]	M/s Biological E. Ltd.	In light of the recommendation of SEC-vaccine meeting dated 26.11.2024, the firm has submitted the revised Phase I clinical trial protocol. The firm presented the revised Phase I clinical trial protocol titled, "A prospective multicentre, open label, Phase-I study to evaluate the safety and immunogenicity of Biological E's Bivalent Typhoid and Paratyphoid A conjugate vaccine administered to 18-55 years-old healthy adults in India." After detailed deliberation, the committee recommended for conduct of the Phase I clinical trial as per the presented protocol.
4.	Human Papillomavirus 9-valent Vaccine, Recombinant (Serotypes: Type 6 L1, 11 L1, 16 L1, 18 L1, 31 L1, 33 L1, 45 L1, 52 L1 and 58 L1) [MA application with Phase IV clinical trial Protocol and Phase III clinical trial waiver] [BIO/IMP/24/000134]	M/s. Merck Sharp & Dohme LLC.	The firm has submitted the application for grant of permission to import Human Papillomavirus 9-valent Vaccine, Recombinant (Serotypes: Type 6 L1, 11 L1, 16 L1, 18 L1, 31 L1, 33 L1, 45 L1, 52 L1 and 58 L1) for additional indication i.e., age expansion and 2-dose regimen) with local Phase III clinical trial waiver and with commitment to conduct a Phase IV clinical trial. The committee observed that 9vHPV vaccine is already approved in three dose schedules for the age group 9 – 15 years (both boys and girls) in India. WHO and other recommending bodies including IAP and FOGSI advise vaccinating individuals aged 9-14 years with 2-dose regimen because this ensures

			protection in this age group before being exposed to HPV. Further, as per the published literature, younger individuals (aged 9-14 years) demonstrate a robust immune response after two doses of the HPV vaccine, which is non- inferior to that achieved with three doses in older adolescents and adults. Considering above, after detailed deliberation, the committee recommended for the approval of two dose schedule of 9vHPV vaccine for the age group of 9 -15 years (both boys and girls) to align with regulatory approvals of major countries and WHO with a condition to conduct Phase IV clinical trial in this age group. Accordingly, the firm shall submit Phase IV clinical trial protocol within 3 months of the grant of permission. The committee noted that 9vHPV vaccine is already approved in female for the age group (16 – 26 years) in a three-dose regimen and hence, no additional permission is required for this group. Further, the committee recommended that the firm should generate data in Indian population for other age groups of males (16 – 45 years) and females (27 – 45 years) for consideration of grant of permission. Accordingly, the firm shall submit Phase III clinical trial protocol.

5.	Diphtheria, Tetanus and Pertussis (Acellular, Component) Vaccine (Adsorbed, reduced antigens content) Ph. Eur. [Brand name: Boostrix]. [PI update] [BIO/PostAppr/VAC/2024/1183]	GlaxoSmithKline Pharmaceuticals Limited (GSK).	Firm presented its proposal for updation of prescribing information for Diphtheria, Tetanus and Pertussis (Acellular, Component) Vaccine (Adsorbed, reduced antigens content). After detailed deliberation, the committee recommended for updation of prescribing information in line with EU SmPC.