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 18.12.2024 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 18.12.2024 and recommended the following:

Sr. No.	Name of Vaccine & File no.	Name of Firm	Recommendations
1	Yellow Fever Vaccine [Phase II interim Clinical Trial Report & Phase II/III clinical trial protocol amendment] [BIO/CT/22/000153] [BIO/PostAppr.2024/35747 & BIO/PostAppr.2024/35820]	M/s Serum Institute Private Ltd., Pune	In light of the recommendation of SEC meeting dated 14.12.2023, permission was granted to conduct Phase II/III clinical trial as per presented protocol with conditions that 1) Firm should submit Phase II study report along with DSMB review for approval before initiation of Phase III. 2) Adverse events of special interest (AESI) of Yellow Fever vaccine to be included in the Patient information sheet. Now, firm has submitted Interim Analysis of Safety and Immunogenicity Study Report (Blinded) (Phase II) along with DSMB recommendations and revised Phase III study protocol. After detailed deliberation, the committee noted the interim results of Phase II clinical trial and recommended for conduct of Phase III clinical trial as per the presented revised protocol.
2	Typhoid Conjugate Vaccine (Bivalent) [Phase I Study report along with Phase II/III protocol] [BIO/CT/24/000153]	M/s Serum Institute of India Private Limited	The firm presented the Phase I clinical trial report along with Phase II/III clinical trial protocol titled, “A Phase II/III, double-blind, randomized, active-controlled, multicentric study to evaluate the safety, immunogenicity and lot to-lot consistency of a bivalent conjugate vaccine against *Salmonella enterica*

			serovars Typhi and Paratyphi A in healthy individuals aged 6 months to 65 years" The committee noted the safety results from Phase I clinical trial report. Further, after detailed deliberation, the committee recommended for approval to conduct Phase II/III clinical trial as per presented protocol with condition that : Firm should submit Phase II study report along with DSMB review for approval before initiation of Phase III study.
3	Measles, Mumps and Rubella vaccine (Live) I.P. (Freeze Dried) [Phase IV Clinical Trial Protocol] [BIO/CT/24/000139]	M/s. Zydus Lifesciences Limited Ltd., Ahmedabad, Gujarat	The firm presented the Phase IV Clinical Trial Protocol titled "A prospective, randomized, parallel, single-blind, two-arm, active controlled, multicentre, Phase IV clinical trial to evaluate the immunogenicity and safety of Measles, Mumps, and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. compared to Measles, Mumps, and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Serum Institute of India Pvt. Ltd. in healthy infants aged 9-12 months" After detailed deliberation, the committee recommended that firm should submit revised protocol with respect to secondary objective, administration of test and reference vaccine and concomitant

			medications for further deliberation.
4	Rabies Vaccine, Human I.P. (Purified Chick Embryo Cell Culture Rabies Vaccine ($PCECV^{PM}$) [Phase IV Clinical Trial Protocol] [BIO/CT/24/000127]	M/s. Zydus Lifesciences Limited Ltd., Ahmedabad, Gujarat	The firm presented the Phase IV Clinical Trial Protocol titled "An open-label, multicentre, Phase IV clinical study to assess the safety and immunogenicity of VaxiRab N® administered for prophylaxis against rabies." After detailed deliberation, the committee recommended for conduct of the study as per the presented protocol with condition to include minimum one-third of female subjects in Pre-exposure prophylaxis (PrEP) arm and additional sites from North-eastern and Southern India to achieve uniform distribution throughout India.