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 29.01.2026 (through hybrid mode)

Recommendations:

The SEC (Vaccine) deliberated the proposals on 29.01.2026 and recommended the following:-

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1	Varicella Vaccine (Live Attenuated) Phase III Clinical Trial Report for New Drug Permission [BIO/IMP/25/000004]	M/s Techinvention Pvt Ltd.	Firm presented Phase III clinical trial report titled, "A prospective, randomized, single blind, parallel, active controlled, multicentre, non-inferiority Phase III study to evaluate the immunogenicity and safety of live attenuated Varicella vaccine of Sinovac Biotech Ltd, China compared to VARIPED® Vaccine (Varicella Vaccine live I.P by MSD Pharmaceuticals Pvt Ltd, India) in healthy paediatric subjects in India". The committee noted that firm has not submitted the following data as per approved protocol in the clinical study report:- (1) age stratified safety data (2) concomitant medication data (3) statistical inference of safety data Also, the committee opined that the firm should submit following information :- (1) stratified demographic, seropositivity and immunogenicity data of the participants age wise (1 - 6 years and 6 - 12 years), (2) data should be presented as mean, median, SD and IQR when presented graphically for comparability of immunogenicity data of test and reference vaccine, (3) the firm should review the demographic data as per WHO recommended age vs weight chart to -2 SD and submit the details of the children below -2 SD weight for age. After detailed deliberation, the committee recommended that the firm should submit the above-mentioned

			data for further deliberation.
2.	Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried) Phase III Clinical Trial Protocol [BIO/CT/25/000094]	M/s Zydus Lifesciences Ltd.	Firm presented Phase III clinical study Protocol titled: "A prospective, randomized, parallel, single-blind, five-arm, active-controlled, multicentre, phase III 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. and to evaluate lot-to-lot consistency of Measles, Mumps and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s. Zydus Lifesciences Ltd. in healthy infants aged 9-12 months". The committee noted the following:- 1. the firm is required to include seropositivity rate, seroconversion rate and GMT as primary endpoints instead of secondary endpoints, 2. the firm is required to revise dropout rate from 20% to 10%. Accordingly, firm should revise the sample size in all cohorts, 3. the firm is required to specify the weight of the healthy children as per WHO recommended age vs weight chart to -2 SD weight for age in the exclusion criteria 4. the firm is required to remove the blood sample withdrawal at 180 days and revise the protocol accordingly in all the relevant sections of the protocol including study procedure, assessment and statistical analysis plan. 5. the firm is required to specify that the GMTs of all antibodies assessed from the samples will be compared between test group and reference group separately for each cohort (batch wise) and also as pooled data.

			In view of above and after detailed deliberation, the committee recommended that the firm should submit revised protocol to CDSCO for further consideration.
3.	Typhoid Vi Conjugate Vaccine with yellow fever vaccine (non- interference study) Phase IV Clinical Trial Report [BIO/PostAppr/2025/43117]	M/s Zydus Lifesciences Ltd	Firm presented report of Phase IV clinical trial titled "A prospective, randomized, parallel, two-arm, open-label, multicenter, phase IV clinical trial to evaluate the immunological non-interference of Typhoid Vi conjugate vaccine with Yellow fever vaccine administered to healthy subjects". After detailed deliberation, the committee noted the results of Phase IV study.
4.	Measles, Mumps, Rubella and Varicella Vaccine Phase I Clinical trial protocol (Re-deliberation) [BIO/CT/25/000048]	M/s Zydus Lifesciences Ltd	In light of recommendation of SEC dated 25.07.2025, firm submitted revised Phase I clinical trial protocol titled, "An open-label, single-treatment, single-period, single dose, clinical phase I study to assess the safety and tolerability of measles, mumps, rubella & varicella vaccine (live attenuated, freeze dried) of M/s. Zydus life sciences Ltd. in healthy, adult, human participants" and presented revised version 2. After detailed deliberation, the committee recommended for conduct of Phase I study as per presented protocol with the condition that the firm should revise seropositivity titre for anti-varicella IgG antibodies as 50 mIU/mL. Accordingly, firm should submit revised protocol to CDSCO for consideration.