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 24.09.2025 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 24.09.2025 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1	Inactivated Kyasanur Forest Disease (KFD) Vaccine Phase I clinical trial protocol [BIO/CT/25/000138]	M/s. Indian Immunologicals Limited	The firm presented Phase I clinical trial protocol titled, "A first-in-human randomized, double-blind, placebo-controlled Phase I study in healthy Indian adults to evaluate the safety, reactogenicity, and immunogenicity of inactivated KFD vaccine developed by the Human Biologicals Institute." The committee noted the following points: 1. Kyasanur Forest Disease (KFD) is a tick borne viral haemorrhagic fever that is endemic to Western Ghats region of primarily Karnataka and other neighboring states like Kerala, Tamilnadu and Goa. 2. The KFD virus is a Flavivirus of family Flaviviridae, vectors of these viruses commonly consist of Haemaphysalis spinigera, Dermacentor and Ixodes ticks. 3. M/s Indian Immunological Limited (IIL) has developed an inactivated adjuvanted KFD vaccine based on live Kyasanur Forest Disease virus strain No.: NIV 164187 isolated by ICMR – NIV, Pune and proposed for first-in human Phase I study in collaboration with ICMR. 4. Firm has conducted pre-clinical toxicity (single dose and repeat dose toxicity) and immunogenicity studies with Inactivated Kyasanur Forest Disease (KFD) vaccine. 5. Based on the toxicity and immunogenicity studies, the vaccine was concluded to be safe, well tolerated and immunogenic. 6. The firm has proposed to conduct first in human study as two dose (≥18 µg each dose) 28 days apart in healthy volunteers (18-49 years of age) in a KFD endemic area.The

			outcome will also provide data relating to the participants who achieve seropositivity as specified in the protocol. 7. As exploratory endpoints, the firm has proposed to compare the immunogenicity in subgroups identified at baseline based on flavivirus serostatus. 8. The study will be continued till 366 days for safety and immunogenicity follow-up. 9. The firm will submit the DSMB report after 57 days to CDSCO before planning for conduct of Phase II clinical trial. 10. The firm has initiated developmental and reproductive toxicology (DART) study. As per clinical trial protocol, female volunteers will be recruited after completion of DART study. In view of above and after detailed deliberation, the committee recommended for conduct of the Phase I clinical trial as per the presented protocol.
2	Inactivated Chikungunya Vaccine Phase I/II clinical trial protocol [BIO/CT/25/000115]	M/s Zydus Life Science Limited	The firm presented Phase I/II clinical trial protocol of the study titled," A prospective, randomized, double-blind, placebo-controlled, phase I/II clinical trial to evaluate the safety and immunogenicity of Chikungunya vaccine candidate of M/s. Zydus Lifesciences Ltd. in healthy participants ". The committee noted the following points: 1. Firm has developed Inactivated Chikungunya Vaccine based on the Chikungunya parent virus seed (DEN-AFP-SV13-0030). 2. The firm has completed acute toxicity study and repeat dose toxicity study before selecting human dose.

			3. The firm has not furnished any lethal dose challenge study report in any animal model and/or in non-human primates for confirmation of human protective dose of this proposed novel inactivated vaccine developed for chikungunya. 4. The firm has not furnished any developmental and reproductive toxicology (DART) study report. 5. The firm has not furnished immunogenicity data for selection of protective dose. 6. Based on the toxicity studies, firm has proposed to conduct Phase I study followed by Phase II study as single dose or two doses study based on data of Phase I trial. 7. As the vaccine is developed from chikungunya virus strain from new source , it was opined that firm should separate Phase I and Phase II protocol and establish safety and tolerability of the vaccine in the first-in human study. 8. The firm should include exploratory endpoint to compare the immunogenicity in subgroups identified seropositive in the baseline which is currently excluded in the protocol. 9. The safety follow up for Phase-I and Phase II should be increased to 6 months / 1 year for adequate safety data for new vaccine. 10. The firm should submit the revised Phase I protocol to conclude the maximum and minimum dose for Phase II. Based on Phase I study report and high & low dose selection, the firm should submit Phase II

			protocol with adequate justification of sample size. 11. The firm should revise the Phase I protocol for estimation of anti-CHIKV antibodies by $PRNT_{50}$ method as secondary objective instead of exploratory objective. 12. The firm should define the $PRNT_{50}$ cutoff value. 13. The firm has proposed to conduct the immunological assessment at IRSHA, Pune as central laboratory for which the firm is required to furnish the prior experience and capacity of the laboratory for development and generation of bioanalytical test results of new vaccines which are standardized, consistent and reproducible. In view of above and after detailed deliberation, the committee recommended that the firm should submit response with respect to the above observations including protective dose selection criteria for the new vaccine. Accordingly, the firm should submit revised Phase I protocol only for further deliberation.
3	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) New Drug Permission (MA) (Addition of alternative dosing schedule) (2+1) (6 weeks, 14 weeks and 9 months) [BIO/MA/25/000121]	M/s Biological. E Limited	The firm has presented the proposal for approval of additional indication i.e., addition of alternative dosing schedule) (2+1) (6 weeks, 14 weeks and 9 months) for Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) along with Phase III clinical trial study report titled “A single blind randomized active-controlled Phase-III study to evaluate immunogenicity, safety, tolerability of a candidate 14valent pneumococcal polysaccharide conjugate vaccine administered to 6-8 weeks old Indian Infants at 6 weeks,

			14 weeks and 9 months of age (2+1 alternative dosing schedule)". The committee noted that the Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) with 3+0 schedule is already approved. After detailed deliberation, the committee recommended that firm should submit additional information w.r.t following points for further deliberation: 1. Detail of causality analysis of the adverse events with case diagnosis where concomitant medications were given to participants during the study period. 2.Comparative safety and immunogenicity data of 3+0 study v/s 2+1 study as per serostatus at baseline.
4.	Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Inactivated Poliomyelitis Vaccine I. P New Drug Permission (additional indication) [BIO/IMP/24/000127]	M/s Sanofi Healthcare India Private Limited.	The firm presented the proposal for approval of the change in indication of Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Inactivated Poliomyelitis Vaccine I.P., as below along with various changes in prescribing information: - • for primary vaccination in infants from the age of 6 weeks • for booster vaccination, one year after primary vaccination during the second year of life, • for booster vaccination between 4-13 years of age, according to official recommendations The committee noted that the vaccine is already approved in India for the following indications : • for primary vaccination in infants from the age of 2 months • for booster vaccination, one year after primary vaccination during the

			second year of life • for booster vaccination between 5 - 13 years of age, according to National Immunization Schedule. After detailed deliberation, the committee recommended for the proposed change in indication and various changes in prescribing information" in line with EU SmPC excluding the statement that "Tetraxim can be used to reconstitute the Haemophilus influenzae type b conjugate vaccine (Act-Hib).