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 19.03.2026 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 19.03.2026 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1.	Dengue tetravalent vaccine (live, attenuated) Permission to Import (new drug permission) along with Phase-III clinical study report in Indian population. [BIO/IMP/24/000037]	M/s Takeda Biopharmaceuticals India Pvt. Ltd.	In light of recommendation of SEC dated 28.08.2025, firm submitted the complete clinical study report for Phase III clinical trial titled "A randomized, double-blind, placebo-controlled, Phase III trial to investigate the safety and immunogenicity of Dengue Tetravalent Vaccine (TDV) administered subcutaneously to healthy subjects aged 4 to 60 in India". The committee noted the following: - 1. The vaccine is approved in 41 countries including EU, UK, Switzerland, Indonesia, Malaysia, Thailand etc. 2. In the EU, the vaccine is indicated for the prevention of dengue disease in individuals from 4 years of age. 3. The vaccine is also WHO pre-qualified and is indicated for the prevention of dengue disease in individuals from 6 years of age. 4. Firm presented efficacy data of test vaccine (4.5 years) of 20,099 participants from Global pivotal Phase III study (DEN-301) conducted in 8 countries including Brazil, Thailand, Srilanka etc. 5. Firm has conducted various phases of clinical trials (9 phase 3 trials, 6 phase 2 trials, and 5 phase 1 trials) globally with more than 28,000 subjects from dengue-endemic and non-endemic regions, and covering an age range from 1.5 to 60 years. Efficacy and/or safety data based on interim or final CSRs are available for 17 trials. 6. Approximately 24.4 million doses of vaccines have been distributed globally since launch. 7. Post-marketing safety profile has remained largely consistent with clinical trials. No new significant safety information has been identified for the important potential risks covered in the risk management plan.

			8. The Phase III study in India was conducted in 480 healthy adults, adolescents and children aged 4 to 60 years in two cohorts to assess the safety and immunogenicity. 9. The vaccine was found to be tolerated, safe and immunogenic in healthy adults, adolescents and children as per the presented report. 10. As per WHO position paper on dengue vaccines, WHO recommends the introduction of vaccine in routine immunization programs in individuals from 6 to 16 years of age in areas where high dengue transmission poses a significant public health problem, without pre-vaccination screening. In view of above and after detailed deliberation, the committee recommended for grant of new drug permission for import of Dengue Tetravalent Vaccine (TDV) in individuals from 4 to 60 years of age with condition that the firm should conduct post marketing safety and effectiveness study in Indian population within six months of introduction of the vaccine in Indian market.
2.	Human Papillomavirus 9-Valent Vaccine, Recombinant [Serotypes 6 L1, 11 L1, 16 L1, 18 L1, 31 L1, 33 L1, 45 L1, 52 L1 & 58 L1] (Gardasil® 9) Phase III Clinical trial protocol [BIO/CT/25/00019]	M/s MSD Pharmaceuticals Pvt. Ltd.	In light of recommendation of SEC dated 26.03.2025, firm has submitted Phase III clinical trial protocol titled “A Phase III open-label study to evaluate the safety and immunogenicity of 9vHPV vaccine administered as 3-dose regimen in 16-to 45-year-old males and 27-to-45-year-old females in India. The committee noted the following: - 1. Human Papillomavirus 9-Valent Vaccine, Recombinant is approved for indication in girls and women from 9 years to 26 years age at 03 dose regimen (schedule: 0, 2 & 6 months) for the prevention of cervical, vulvar, vaginal and anal cancer; precancerous or dysplastic lesions; genital warts and persistent infections caused by Human Papillomavirus (HPV) and in boys from 9 years to 15 years at 03 dose regimen (schedule: 0, 2 & 6 months) for the prevention of external genital lesions and

			persistent infections and other diseases caused by HPV types. 2. The vaccine is also approved for two dose schedule in the age group of 9 - 15 years (both boys and girls). During the deliberation, the committee made the following observations: - 1. The firm has proposed to conduct the study in three cohorts and the sample size proposed is not adequate for an evaluable outcome. Hence, the number of participants should be well representative of the population of that particular age group in the country. 2. The clinical trial sites should be geographically distributed across the country. 3. Determination of seroconversion and GMT should be included as the primary objective of the study protocol. 4. The firm should plan and conduct immune persistence study as secondary objective in the Indian Population. In view of above, the committee recommended that the firm should submit revised protocol for further deliberation.
3.	Inactivated Chikungunya Vaccine Phase I Clinical trial protocol as per SEC recommendation. (Re-deliberation) [BIO/CT/25/000115]	M/s Zydus Lifesciences Limited	In light of recommendation of SEC dated 24.09.2025, firm submitted revised Phase I clinical trial protocol of the study titled, "A prospective, randomized, double-blind, placebo-controlled, phase I clinical trial to evaluate the safety and immunogenicity of Chikungunya vaccine candidate of M/s. Zydus Lifesciences Ltd., in healthy human participants". The committee noted the following: 1. M/s Zydus Lifesciences Limited has developed Vero Cell based Inactivated Chikungunya Vaccine from Chikungunya parent virus seed (DEN-AFP-SV13-0030). 2. Firm has completed single dose acute toxicity, repeated dose toxicity and immunogenicity studies in animal species. Based on the toxicity studies conducted in 6 times higher doses, firm

			has proposed to conduct Phase I study as two doses in three cohorts in healthy volunteers (18-50 years of age). 3. The firm will submit interim analysis report of immunogenicity data till 28 days after 2nd dose and safety data till 84 days after 2nd dose along with the DSMB report to CDSCO before planning for conduct of Phase II clinical trial. After detailed deliberation, the committee recommended for conduct of Phase I study as per presented protocol with the conditions to complete the following studies before proceeding to clinical studies in larger populations (1) lethal dose challenge study 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 (2) developmental and reproductive toxicology (DART) study (3) immunogenicity data for confirmation of protective dose.
4.	Meningococcal Polysaccharide (Serogroups A, C, Y and W135) Tetanus Toxoid Conjugate Vaccine Permission to Import (new drug permission) along with Phase III Global Clinical Study Report (Re-deliberation) [BIO/IMP/25/000030]	M/s Sanofi Healthcare India Pvt. Ltd	In light of recommendation of SEC dated 29.04.2025 and 27.10.2025, firm submitted global vis-à-vis Indian population data after extraction from the global data as a supplement to clinical study report. The committee noted the following: - 1. Meningococcal Polysaccharide (Serogroups A, C, Y and W135) Diphtheria Toxoid Conjugate Vaccine is already approved in India. Now, the firm has developed the product in conjugation with Tetanus Toxoid. 2. The product with Tetanus Toxoid is already approved globally in different countries as single dose administration for active immunization for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W and Y in individuals 6 weeks of age and older in US and 12 months and older in EMA, Canada.

			3. The vaccine is also WHO pre-qualified and is indicated for active immunization of individuals from the age of 12 months and older against invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W, and Y. 4. Firm has distributed more than 30 million doses globally, since launch of the product. 5. The study in Indian Population was conducted in 866 healthy adults (aged 18 years and above), adolescents, and children (aged 2 to 17 years). 6. The immunogenicity of test vaccine was found to be non-inferior to that of comparator vaccine for serogroups A, C, Y, and W when administered as a single dose in children and adolescents aged 2 to 17 years in India. 7. The immune response of test vaccine was comparable to that induced by comparator vaccines in Indian adults. 8. The safety profile of test vaccine in adult and paediatric populations was comparable to that of comparator vaccines. In view of above and after detailed deliberation, the committee recommended for grant of new drug permission for import of Meningococcal Polysaccharide (Serogroups A, C, Y and W135) Tetanus Toxoid Conjugate Vaccine for active immunization for the prevention of invasive meningococcal disease caused by Neisseria meningitidis serogroups A, C, W and Y in individuals aged 2 years and older.
5.	Pneumococcal polysaccharide conjugate vaccine I.P (PCV 13-TT) adsorbed Additional booster Indication (Re-deliberation) [BIO/PostAppr/2025/40607] [BIO/IMP/25/000130]	M/s G. C. Chemie Pharmie Ltd.	In light of recommendation of SEC dated 27.10.2025, firm presented the following: - 1. Comparative safety and immunogenicity data of 3+1 study v/s 3+0 study as per serostatus at baseline. 2. The details of concomitant medication and vaccination as per the protocol. 3. Published data / literature showing long term persistence of immunogenicity after the booster dose.

			The committee noted that the vaccine is approved in India for active immunization against disease caused by Streptococcus pneumonia serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 23F in infants from 6 weeks of age group for 3 dose regimen (dosing schedule 6, 10 and 14 weeks). In view of above and after detailed deliberation, the committee recommended for grant of permission for booster dose of Pneumococcal polysaccharide conjugate vaccine I.P (PCV 13-TT) adsorbed at 15-18 months of age.