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 27.10.2025 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 27.10.2025 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1	Live Attenuated Tetravalent Recombinant Dengue Vaccine -freeze dried Phase II/III Clinical trial protocol [BIO/CT/25/000131]	M/s. Indian Immunologicals Limited	Earlier, this office had granted permission for conduct of Phase I clinical trial "A Phase I single blind randomized placebo-controlled study to evaluate the safety and immunogenicity of Live attenuated tetravalent recombinant Dengue vaccine of HBI in healthy adults of 18 to 50 years of age." Now, the firm presented Phase I clinical study report along with Phase II/III clinical trial protocol titled, “A double-blind randomized multicentric placebo-controlled seamless Phase II/III clinical trial to evaluate the immunogenicity, efficacy and safety of live attenuated tetravalent recombinant dengue vaccine of HBI in healthy subjects.” During deliberation, the committee made the following observations:- 1. The firm has proposed to conduct Phase II clinical trial with two compositions of the study vaccine coded as HBI-DV-TV003 and HBI-DV-TV005 (with difference in concentration of rDENV2) in three age groups along with Placebo with safety as primary objective. However, justification for selection of two composition is not clearly defined in the protocol. 2. Further, the firm has proposed to conduct Phase III clinical trial with safer and superior formulation selected on the basis of DMC recommendations after review of interim analysis data of Phase II. 3. The firm has completed the Phase I clinical trial in healthy adults of 18

			to 50 years of age group with the composition HBI-DV-TV005 of the study vaccine and study results were noted by the committee. In view of above and after detailed deliberation, the committee recommended the following:- 1. The Phase II study protocol should include Seropositive as well as Seronegative individuals and the inclusion criteria should be revised accordingly. 2. The firm should separate Phase II and Phase III protocols and submit revised Phase II protocol only including age de-escalation methodology (higher age group followed by the lower age group). 3. The randomization ratio of 2:2:1 should be applied at each study site (or geographically located sites) and the sample size should be calculated accordingly to provide adequate power. 4. The firm should define the independent DMC team (statistical analysis group and safety group) for unblinding the study for selection of superior formulation in the Phase II protocol. Accordingly, firm shall submit revised Phase II protocol for further deliberation. [Dr. Vineeta Bal did not participate in the deliberation.]
2	Quadrivalent Human Papilloma Virus Serotypes 6,11,16 & 18 Vaccine Recombinant I.P Phase III clinical trial Protocol (Additional	M/s Serum Institute of India Pvt Ltd	The firm presented Phase III clinical trial protocol of the study titled, "A Phase-III, double-blind, randomized, active-controlled, multicentric clinical trial to evaluate the immunogenicity and safety of SIIPL's qHPV Vaccine (CERVAVAC) administered intramuscularly in women aged 27 to 45 Years as compared to Merck's HPV 6/11/16/18 Vaccine

	Indication: Women of child bearing age of 27-45 years old). [BIO/CT/25/000140]		(Gardasil)." After detailed deliberation, the committee made the following observations and recommendations: - 1. The study vaccine is already approved in the age group of 9-14 years (male and female), at two-doses schedule (0 and 6 months) and for age group of 15-26 years (male and female), at three-dose schedule (0, 2 and 6 months) for prevention of the disease caused by Human Papilloma Virus types 6, 11, 16 and 18. 2. The primary objective of the present study is to demonstrate that the immune response to HPV types 16 and 18 among women receiving CERVAVAC is non-inferior to that in the women receiving Gardasil and one of the secondary objectives is to demonstrate that the immune response to HPV types 6 and 11 among women receiving CERVAVAC is non-inferior to that in the women receiving Gardasil. The firm should include determination of immune response to HPV types 6 and 11 as primary objective instead of secondary objective. 3. Similarly, the firm should consider assessing the protection against incident persistent cervical HPV 6, 11, 16 and 18 infections in women receiving CERVAVAC and Gardasil at 24, 36 months as secondary objective instead of exploratory objective for serotypes 6 and 11 infections. 4. The non-inferiority criteria defined in the current protocol with respect to GMT ratio is ≥ 0.5 instead of ≥ 0.67 and the firm has not included the non-inferiority criteria as the lower bound of 95 % confidence interval

			(CI) of seroconversion rate difference > -10 % and the same should be revised accordingly. 5. The firm should carry out additional blood sampling prior to third dose for determination of immunogenicity after two doses and comparing the same with immunogenicity after third dose. In view of above, the firm should submit revised protocol to CDSCO for further review.
3	Pneumococcal polysaccharide conjugate vaccine I.P (PCV 13-TT) adsorbed New drug permission for booster dose along with Phase III clinical study report. [BIO/PostAppr/2025/40607] [BIO/IMP/25/000130]	M/s G. C. Chemie Pharmie Ltd.	The firm presented booster dose administration study as per the recommendations of SEC (Vaccine) dated 21.02.2022 for the study titled, "A Randomized, double-blind, multi-center, Phase III study to assess and compare the immunogenicity and safety of the 13-Valent Pneumococcal Polysaccharide conjugate vaccine (PCV13-TT) with PREVENAR 13 of Pfizer Inc. in healthy infants in India". After detailed deliberation, the committee recommended that the firm should submit the following additional information for further deliberation: - 1. Comparative safety and immunogenicity data of 3+1 study v/s 3+0 study as per serostatus at baseline. 2. The firm should provide details of concomitant medication and vaccination as per the protocol. 3. Published data / literature showing long term persistence of immunogenicity after the booster dose.
4.	Meningococcal Polysaccharide (Serogroups A, C, Y and	M/s Sanofi Healthcare India Private Limited.	In light of the recommendation of SEC (Vaccine) on 29.04.2025, the firm has submitted: -

	W135) Tetanus Toxoid Conjugate Vaccine Re-deliberation in light of SEC vaccine recommendation dated, 29.04.2025. [BIO/IMP/25/000030]		1) The non-inferiority of hSBA vaccine sero protection after vaccination for Indian population of 2–17 years age group. 2) The comparability clinical trial data summary of Indian and global population for the age group of above 55 years. After detailed deliberation, the committee observed that the firm has submitted a consolidated overview of the above information instead of presentation of global vis-à-vis Indian population data after extraction from the global data. Accordingly, the committee recommended that firm should submit detailed data as a supplement to clinical study report for further deliberation.