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 22.08.2024 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 22.08.2024 and recommended the following:

Sr.No.	Name of Vaccine & File no.	Name of Firm	Recommendations
1	Hepatitis A (Live) Vaccine, Freeze-Dried Injection [MA] [BIO/IMP/24/000049]	M/s Joint Force Pharmachem Pvt. Ltd., Mumbai	The firm presented its proposal for grant of permission to import Hepatitis A (Live) Vaccine, Freeze-Dried for sale and distribution along with report of Phase III clinical trial conducted in India. After detailed deliberation, the committee opined that the firm should submit following information/clarification for further deliberation: 1) Data of screened subjects along with age and other demographic details who did not meet the inclusion criteria. 2) Age wise stratified data for sero-protection and sero-conversion achieved in the study population. 3) Published literature of clinical trial data for the vaccine. 4) Details of dose administered in country of origin and outside.
2	Diphtheria Tetanus and Pertussis (Whole cell) Hepatitis-B (rDNA) Haemophilus Influenzae Type b Conjugate and Inactivated Poliomyelitis Vaccine (Adsorbed) (DTwP-HepB-HibI-PV) [Phase-I Clinical Trial Protocol]	M/s Indian Immunological Limited, Hyderabad	The firm presented the Phase I Clinical Trial Protocol for Diphtheria Tetanus and Pertussis (Whole cell) Hepatitis-B (rDNA) Haemophilus Influenzae Type b Conjugate and Inactivated Poliomyelitis Vaccine (Adsorbed) (DTwP-HepB-HibIPV) for study titled “An open label Single

	[BIO/CT/24/000080]		Centric Phase I Clinical Trial to evaluate the safety and immunogenicity of Hexavalent (DTwP-HepB-Hib-IPV) vaccine of HBI when administered in Healthy Subjects from 16 months to 24 months of age". After detailed deliberation, the committee opined that the firm should submit following information/clarification : 1) the selection of proposed age group for Phase I trial as 16 to 24 months and as booster dose which is not recommended age group of IPV in the country. 2) Reasons for selecting lower age group for a new vaccine in Phase I trial instead of higher age group. 3) Reasons for not including active monitoring of adverse events for assessment of safety in the Phase I trial design. 4) More details on the source of IPV which is not approved in India and the population in which IPV has been administered and doses administered other than country of origin.
3	Live Attenuated Varicella Vaccine [MA] [BIO/IMP/24/000070]	M/s NOVO Medi Sciences Private Limited	The firm presented the Phase III clinical trial report of Live Attenuated Varicella Vaccine of study titled "A Prospective, Randomized, Observer Blind, Parallel, Active Controlled, Multicentre, Non-Inferiority Phase III study to evaluate the

			immunogenicity and safety of Live Attenuated Varicella Vaccine of Novo Medi Sciences Pvt. Ltd compared to a marketed Varicella Vaccine (VARIPED®) in healthy subjects". After detailed deliberation, the committee noted the results of Phase-III clinical trial conducted in country and recommended for grant of import permission for Live Attenuated Varicella Vaccine with changed composition of inactive ingredients.
4	Live Attenuated Varicella Vaccine [Phase-III Clinical Trial Protocol] [BIO/CT/24/000037]	M/s. Dr Reddy's Laboratories Limited, Hyderabad	In light of recommendation of SEC meeting dated 31.05.2024, the firm presented the revised Phase III clinical trial protocol of Live Attenuated Varicella Vaccine of study titled "A Phase III, multicentre, randomized, observer - blind, active-controlled, parallel group, non-inferiority study to evaluate immunogenicity and safety of Varicella vaccine (BARYCELA) in Healthy Pediatric Population 12 months to 12 years of age". After detailed deliberation, the committee recommended for approval of presented Phase-III clinical trial protocol with condition to conduct immunogenicity analysis for all proposed 500 evaluable subjects in part 2 of the trial with age stratification of all proposed age group.

			Accordingly, revised protocol should be submitted to CDSCO for further approval.
5	Tetanus Toxoid, Reduced Diphtheria Toxoid & Acellular Pertussis Vaccine Adsorbed (Adacel®) [PI Update] [12-168/Sanofi/PAC-Many Vac/16-BD(I)]	M/s Sanofi Healthcare India Private Limited	Firm presented its proposal for updation of prescribing information of Tetanus Toxoid, Reduced Diphtheria Toxoid & Acellular Pertussis Vaccine Adsorbed. After detailed deliberation, the committee recommended to submit 1. Data/publications in support of the proposed changes. 2. Post marketing surveillance data in Indian Population.