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 31.05.2024 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 31.05.2024 and recommended the following:

Sr. No.	Name of Vaccine &File no.	Name of Firm	Recommendations
1	Dengue Tetravalent Vaccine (Live, Attenuated) [Phase I interim Clinical Trial Report] [BIO/CT/23/000007 (BIO/PostAppr/2024/32827)]	M/s Serum Institute Private Ltd., Pune	In light of recommendation of the SEC dated 18.07.2023 , the firm presented Phase I interim Clinical Trial Report of Dengue Tetravalent Vaccine (Live, Attenuated) After detailed deliberation, the committee noted the results of Phase I interim clinical trial and recommended for continuation of Phase II clinical trial as per approved protocol.
2	Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted) [Phase-III Clinical Trial Protocol (redeliberation)] [BIO/CT/23/000155]	M/s GSK Pharma India Private Limited, Mumbai	In light of the recommendation of SEC (vaccine) meeting dated 27.02.2024, the firm presented the revised Phase-III Clinical Trial Protocol titled “A Phase III, randomized, placebo-controlled, observer blind study in India to evaluate immune response, reactogenicity and safety of a single intramuscular dose of RSVPreF3 OA investigational vaccine when administered to older adults ≥60 years of age and adults 50-59 years of age at increased risk of respiratory syncytial virus lower respiratory tract disease”. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-III clinical trial as per presented protocol. The firm should include clinical trial sites from various states of southern part of India.

3	Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) I.P. [Phase-I Clinical Trial Protocol] [BIO/CT/24/000041]	M/s Human Biologicals Institute, Telangana	The firm presented the Phase-I Clinical Trial Protocol for Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) I.P. of study titled "An open label single centric Phase I clinical trial to evaluate the safety and immunogenicity of Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) of HBI when administered in two groups of healthy subjects", along with pre-clinical data. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-I clinical trial as per presented protocol with the condition that the firm should conduct the Phase I trial in the age group of 18 to 49 years followed by DSMB review before initiation of the trial in age group of 12 to <18 years. Accordingly, firm should submit revised protocol to CDSCO.
4	Live Attenuated Varicella Vaccine [Phase-III Clinical Trial Protocol] [BIO/CT/24/000037]	M/s Dr Reddy's Laboratories Limited, Hyderabad	The firm presented the Phase-III Clinical Trial Protocol 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" along with non-clinical and clinical study conducted in Korea and Thailand. After detailed deliberation, the committee recommended to revise

			the protocol: 1) to include safety cohort of total 100 subjects in higher age group of the 12 months to 12 years age group with test and control arm and complete safety study with DSMB review before initiation of the immunogenicity and safety study in the targeted age group. 2) to increase the number of subjects 3) to include more clinical trial sites representing all geographical regions including eastern part of India.
5	Oral Rotavirus Vaccine Live oral (ORV) 116E (ROTAVAC®) PI Update. [12-90/BBIL/PAC-Rotavirus/23-BD]	M/s Bharat Biotech International Limited, Hyderabad	The firm presented prescribing information of Rotavirus vaccine for updation based on WHO position paper, July 2021. After detailed deliberation, the committee recommended to submit safety data of Rotavirus vaccine in age group of 1 to 2 years including published literature report for further review.
6	VAC52416 (JNJ-78901563 [ExPEC9V]) [Clinical trial Protocol Amendment] [GCT/PostAppr/2024/31249 CT/14/23-DCG (I)]	M/s Pharmaceutical Research Associates India Pvt. Ltd.	The firm presented protocol amendment 7 dated 17 November 2023 protocol no. VAC52416BAC3001. After detailed deliberation, the committee recommended protocol amendment as presented by the firm. Further, the firm should submit subset analysis of the Indian population additionally.