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 30.04.2024 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 30.04.2024 and recommended the following:

Sr. No.	Name of Vaccine &File no.	Name of Firm	Recommendations
1	Recombinant Hepatitis E Vaccine [MA] [BIO/IMP/23/000032]	M/s Urihk Pharmaceutical Private Limited, Mumbai	In light of recommendation of SEC vaccine meeting dated 27.06.2023, inspections of clinical trial sites were conducted by CDSCO. The committee noted the outcome of inspections. After detailed deliberation, based on the outcome of the inspection and the clinical study report submitted, the committee recommended for grant of import permission of the Recombinant Hepatitis E Vaccine for age group of 18 years to 65 years with condition to conduct Phase IV clinical trial with safety and immunogenicity as primary endpoints on at least 1000 subjects. The protocol for Phase IV clinical trial should be submitted within 2 months and data from this trial should be submitted forthwith for continuing the import and marketing permission.
2	Mycobacterium Tuberculosis (Live Attenuated) Vaccine [Phase-II Clinical Trial Protocol] [BIO/CT/24/000042]	M/s Bharat Biotech International Ltd, Hyderabad	The firm presented Phase I clinical trial report with 28 days safety results along with Phase II clinical trial protocol titled “A Phase II, randomized, double-blind trial to assess the Safety and Immunogenicity of MTBVAC (BBV169), with BCG vaccine as a comparator in Healthy adolescent and adult populations”. The committee noted the results of Phase I Clinical trial report with 28

			days safety results as per the approved protocol. After detailed deliberation of the Phase II protocol, the committee recommended for grant of permission to conduct Phase-II clinical trial as per protocol presented with following conditions: 1) Exclusion criteria should be revised to mention clearly (a) HIV positive subjects will be excluded from the study. b) Diabetic subjects will be excluded. 2) Molecular based RT-PCR test should be performed instead of Sputum AFB smear test for diagnosis of TB. 3) DSMB review should be performed after day 28 and day 56 follow up and same should be submitted to CDSCO at the time of Phase III clinical trial application. Accordingly, revised Phase II protocol should be submitted to CDSCO for approval.
3	Monovalent recombinant Hepatitis-B vaccine [PMS report] [BIO/CT/23/000074]	M/s Biological E. Limited, Hyderabad	The firm presented the post marketing surveillance report of Monovalent recombinant Hepatitis-B vaccine of study titled “A multicentre single arm, post marketing surveillance study to evaluate the safety of Biological E’s Monovalent recombinant Hepatitis-B vaccine when administered to 6-8 weeks old infants in 6-10-14 weeks dosing schedule”.

			After detailed deliberation, the committee noted the results of PMS study as presented by the firm. (Dr Savita Verma didn't participate in the deliberation).
4	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) IP (14 Valent) [Phase-IV Clinical Trial Protocol] [BIO/CT/24/000027]	M/s Biological E. Limited, Hyderabad	The firm presented the Phase IV clinical trial protocol titled "A Phase-IV multicentre follow-up study to assess the continued safety of Biological E's 14-valent pneumococcal polysaccharide conjugate vaccine in subjects, who received 3-dose (3+0) primary PCV vaccination as part of BECT051 and BECT061 studies". After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV clinical trial as per presented protocol.
5	Inactivated Trivalent Influenza vaccine [MA] [12-17/Cadila/16-BD]	M/s Zydus Lifesciences Limited, Ahmedabad	The firm presented the proposal for approval of additional indication for already approved Trivalent Influenza vaccine in age group of 6 months to 17 years. The committee noted that the firm is already having manufacturing permission of Inactivated Quadrivalent Influenza vaccine for the same age group. The applied Inactivated Trivalent Influenza vaccine has same composition as the approved Quadrivalent Influenza vaccine except that it does not contain the B/Yamagata strain. Further, the committee also noted WHO recommendations for use of

			Trivalent Influenza vaccine instead of Quardivalent Influenza vaccine from 2024 onwards. After detailed deliberation and based on the above, the committee recommended for approval of the additional indication in age group of 6 months to 17 years with clinical trial waiver with condition to conduct Phase IV Clinical trial and the clinical trial protocol should be submitted within 3 months.