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 27.03.2024 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 27.03.2024 and recommended the following:

Sr. No.	Name of Vaccine &File no.	Name of Firm	Recommendations
1	Bivalent Typhoid and Paratyphoid A Conjugate Vaccine [Phase I clinical trial protocol] [BIO/CT/24/000013]	M/s Zydus Lifesciences Limited, Ahmedabad	The firm presented the Phase I clinical trial protocol titled "An open-label, single-treatment, single-period, single dose, clinical phase 1 study to assess the safety and tolerability of Bivalent Typhoid and Paratyphoid A Conjugate Vaccine (BTPT) of M/s Zydus Lifesciences Ltd., India in healthy, adult human subjects" along with pre-clinical study report of Bivalent Typhoid and Paratyphoid A Conjugate Vaccine. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-I clinical trial of Bivalent Typhoid and Paratyphoid A Conjugate Vaccine with condition to make screening up to day -14 instead of day - 28. Accordingly, firm should submit revised protocol to CDSCO.
2	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (24 Valent) [Phase – II Clinical trial protocol along with Phase I clinical trial report] [BIO/CT/24/000001]	M/s Biological E. Limited, Hyderabad	The firm presented the Phase I clinical trial report along with Phase II clinical trial protocol titled "An open label randomised Phase-II study to evaluate safety, reactogenicity and immunogenicity of Biological E's 24-valent pneumococcal polysaccharide conjugate vaccine when administered to 6-8 weeks old healthy Indian infants in 6-10-14 weeks dosing schedule" of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (24 Valent).

			The committee noted the safety results from Phase-I clinical trial report. Further, after detailed deliberation of the Phase II protocol presented by the firm, the committee recommended for grant of permission to conduct Phase-II clinical trial with condition to remove blood sample withdrawal post 28 days of 2nd dose. Accordingly, firm should submit revised protocol to CDSCO.
3	Cholera vaccine (Inactivated, Oral) [MA] [BIO/MA/23/000032]	M/s Bharat Biotech Limited, Hyderabad	In light of recommendation of SEC-Vaccine meeting dated 18.07.2023, inspections of clinical trial sites were conducted by CDSCO. The committee noted the outcome of inspections. Further, the firm presented the Phase-III clinical trial report, including immunogenicity and safety results as per the approved protocol for grant of manufacturing permission of Cholera vaccine (Inactivated, Oral). After detailed deliberation, the committee recommended for grant of manufacturing permission of Cholera vaccine (Inactivated, Oral) for age group of 1 year and above. [Dr. Savita Verma didn't participate in the deliberation.]
4	SII-Measles-Mumps-Rubella vaccine and SII-Measles-Rubella vaccine with PRIORIX (GSK) [Phase-IV Clinical TrialProtocol]	M/s Serum Institute of India Pvt. Ltd., Pune	The firm presented the Phase IV clinical trial protocol titled "A Phase IV, double blind, randomized, active control clinical study comparing safety and immunogenicity of SII-Measles, Mumps and Rubella

	[BIO/CT/24/000018]		vaccine and SII-Measles-Rubella vaccine with PRIORIX (GSK) in healthy infants in India" After detailed deliberation, the committee observed that : 1) For the first primary objective -to demonstrate the immunological non-inferiority of two doses of SII-MMR vaccine over two doses of Priorix in infants for all three components of vaccine, the protocol design is acceptable. 2) For the second primary objective - to demonstrate the immunological non-inferiority of two doses of SII-MR vaccine over two doses of Priorix in infants for the two components of vaccine, the protocol should be revised to compare the bivalent MR vaccine of SIIPL with an approved bivalent MR vaccine instead of MMR vaccine. In view of above, the committee recommended that firm should submit two separate protocols as per the above observations of the committee for further deliberation.