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 25.06.2024 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 25.06.2024 and recommended the following:

Sr. No.	Name of Vaccine &File no.	Name of Firm	Recommendations
1	Fully Liquid Pentavalent DTwP-HepB-Hib Vaccine [MyFiveTM] [Phase-II/III Clinical Trial Protocol] [BIO/CT/23/000146]	M/s Panacea Biotec Ltd., New Delhi	The proposal was deferred as per request of the firm.
2	Typhoid and Paratyphoid A Conjugate Vaccine Bivalent [Phase-II Clinical Trial Protocol] [BIO/CT/24/000036]	M/s Biological E. Limited, Telangana	The firm presented interim Phase-I clinical trial report conducted in Europe along with Phase-II Clinical Trial Protocol titled "A prospective multicentre, observer blind, Phase-II study to evaluate the safety and immunogenicity of Biological E's Bivalent Typhoid and Paratyphoid A conjugate vaccine when administered to healthy adults, children/ adolescents and infants/ toddlers in India". After detailed deliberation, the committee recommended to submit complete Phase-I clinical trial report conducted in Europe for further deliberation of the proposal.
3	Quadrivalent Influenza Vaccine (QIV), (Split virion, inactivated) [Phase-III Clinical Trial Report] [BIO/IMP/20/000032]	M/s Sanofi Healthcare India Pvt. Ltd., Mumbai	The firm presented Phase III clinical trial report of Quadrivalent Influenza Vaccine (QIV), (Split virion, inactivated) of study titled "Immunogenicity and Safety of the Quadrivalent Inactivated Split-Virion Influenza Vaccine in Participants 6 months of age and older in India.

			After detailed deliberation, the committee noted that due to sample management issues at one site, 53 subjects' data, was excluded from data analysis and hence, the sample size analysis did not meet the requirements as per approved protocol. In view of above, the committee recommended to complete the clinical trial as per approved protocol with inclusion of new clinical trial site at same geographical location. Accordingly, firm should submit application to CDSCO for protocol amendment.
4	Measles and Rubella vaccine (Live) I.P. (Freeze Dried) [PMS Report] [BIO/PostAppr/2024/32117 [BIO/CT/22/000078]	M/s Zydus Lifesciences Limited, Ahmedabad	The firm presented the PMS study report titled "An active post-marketing surveillance study to evaluate the safety of Measles & Rubella vaccine (Live) I.P. (Freeze Dried) of M/s Zydus Lifesciences Limited in healthy subjects aged 9-12 months." After detailed deliberation, the committee noted the results of Post Marketing Surveillance study.