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 24.06.2025 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 24.06.2025 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1	Equine Klebsiella Immunoglobulin Injection Phase I Clinical Trial Protocol BIO/CT/24/000069	M/s. Bharat Serums and Vaccines Limited,	The firm submitted application for grant of permission to conduct Phase I clinical trial along with preclinical studies report. The firm presented the protocol titled, “An open label, Phase I clinical study to evaluate the safety, tolerability and pharmacokinetics of different strengths of Equine Klebsiella Immunoglobulin Injection in adult healthy volunteers”. The committee noted the following: 1. The proposed product is an equine based polyclonal antibody, which has been developed by using different strains of Klebsiella pneumonia from clinical isolates and ATCC / NCTC. 2. The firm has submitted preclinical studies (acute toxicity and repeat dose toxicity studies and efficacy studies) to determine the human dose for initiating the Phase I study. After detailed deliberation, the committee recommended for conduct of proposed Phase I clinical trial as per presented protocol.

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Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
2	Rabies Vaccine, Human, I.P. Phase I/II Clinical Trial Protocol BIO/CT/25/000034	M/s. Reliance Life Sciences Pvt Ltd.	The firm presented Phase I/II clinical trial protocol titled "A prospective seamless Phase I/II clinical trial to evaluate safety and immunogenicity of Purified Vero Cell Rabies Vaccine (PVRV)(Human)(R-VAC-002) of Reliance Life Sciences Pvt. Ltd.in comparison with Rabivax-S® of Serum Institute of India Pvt. Ltd. in healthy adult subjects". After detailed deliberation, the committee recommended that the firm should conduct Phase I clinical trial as safety and tolerability study in healthy subjects and submit Phase I report along with DSMB recommendations. Accordingly, the firm shall submit revised Phase I protocol instead of Phase I/II protocol to CDSCO.
3.	Respiratory Syncytial Virus Perfusion F Subunit Vaccine (RSVPref) (PF06928316) (Abrysvo®) Phase-III clinical trial protocol BIO/CT/25/000052	M/s Pfizer Limited	The firm presented Phase III clinical trial protocol, titled "A Phase 3 Study in India to describe the safety and immunogenicity of Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine in adults". The committee noted that the product is approved in various countries namely USA, Europe, Japan, Canada, Brazil, Thailand etc. After detailed deliberation, the committee recommended for conduct of proposed Phase III clinical trial with condition that the firm shall specify the number of subjects with preexisting stable disease.

			Accordingly, the firm shall submit revised protocol to CDSCO.
4.	Typhoid Bivalent Conjugate Vaccine Phase I Clinical Trial Protocol BIO/CT/25/000046	M/s Human Biologicals Institute, Rakshapuram, Gachibowli, Telangana	The firm presented Phase I clinical trial protocol titled "An open label Phase I study to evaluate the safety and immunogenicity of Typhoid bivalent conjugate vaccine of HBI when administered to healthy male subjects of 18 to 50 years of age". The committee noted that, (i) The firm has completed preclinical studies (single dose toxicity and repeat dose toxicity studies in rodent and non-rodent species). (ii) The firm proposes to conduct the Phase I trial with both single and multi-dose presentation. After detailed deliberation, the committee recommended for conduct of proposed Phase I clinical trial as per presented protocol.