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 26.11.2024 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 26.11.2024 and recommended the following:

Sr. No.	Name of Vaccine &File no.	Name of Firm	Recommendations
1	20-Valent Pneumococcal Conjugate Vaccine (20vPnC) [MA along with Phase III CT report] [BIO/IMP/24/000060]	M/s Pfizer Limited, Mumbai	In light of recommendation of SEC-vaccine meeting dated 31.07.2024, firm presented the global immunogenicity data of all subjects vis-à-vis immunogenicity data of Indian subjects for 20-Valent Pneumococcal Conjugate Vaccine (20vPnC) and the immunogenicity data of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. 13 valent. After detailed deliberation and based on the data presented, the committee noted the results and recommended for grant of import permission of 20-Valent Pneumococcal Conjugate Vaccine (20vPnC).
2	Diphtheria, Tetanus, Pertussis (whole cell), Hepatitis B (r DNA) and Haemophilus influenza Type b Conjugate Vaccine (Adsorbed) IP [Brand name: MyFive™].) [MA along with Phase I CT report] [BIO/MA/24/000091]	M/s Panacea Biotec Ltd.,	Firm presented its proposal for grant of permission to manufacture Diphtheria, Tetanus, Pertussis (whole cell), Hepatitis B (r DNA) and Haemophilus influenza Type b Conjugate Vaccine (Adsorbed) IP [Brand name: MyFive™] along with request of waiver of Phase II/III clinical trial of vaccine along with the Phase I clinical trial report titled, “An open label, non-comparative, phase I study to evaluate the safety and tolerability of a fully liquid Pentavalent DTwP-HepB-Hib Vaccine (MyFive™, Panacea Biotec Ltd.) in Healthy Subjects 15-18 months of Age.”

			After detailed deliberation, the committee recommended that the firm should conduct Phase I clinical study with the new formulation of the vaccine. Accordingly, firm should submit Phase I clinical trial protocol to CDSCO for further deliberation.
3	Quadrivalent HPV vaccine [Phase I CT Protocol] [BIO/CT/24/000113]	M/s. Cadila Pharmaceuticals Limited Ahmedabad	The firm presented the Phase I clinical trial protocol titled, "A Phase I, open label clinical trial to assess the safety and immunogenicity of Quadrivalent Human Papillomavirus (HPV) vaccine in healthy subjects." After detailed deliberation, the committee recommended for conduct of the Phase I clinical trial as per the presented protocol.
4	Rabies Vaccine, Human I.P.(Purified Chick Embryo Cell Culture Rabies Vaccine($PCECV^{PM}$) [Phase-IV Clinical Trial Protocol] [BIO/CT/24/000121]	M/s. Zydus Lifesciences Limited Ltd.	The firm presented the Phase IV clinical trial protocol titled, "A prospective, randomized, single-blind, parallel, active-controlled, multicentre, Phase IV clinical study to evaluate the long-term immunogenicity and safety of VaxiRab N® compared to a WHO prequalified rabies vaccine in animal bite cases." After detailed deliberation, the committee recommended for conduct of the Phase IV clinical trial as per the presented protocol.
5	Cholera Vaccine (Inactivated *Vibrio cholerae*, MS 1568, Oral) [Addendum safety study report of approved Phase III Clinical trial]	M/s Bharat Biotech International Limited, Hyderabad	In light of recommendation of SEC-Vaccine meeting dated 21.12.2022, firm submitted additional safety data of 1800 subjects as a part of addendum to Phase III clinical trial protocol.

	[BIO/CT/22/000103]		After detailed deliberation, the committee noted the results of the Phase III safety addendum study report. (Dr Savita Verma didn't participated in deliberation)
6	Typhoid and Paratyphoid A Bivalent Vaccine [Phase I/II Clinical trial protocol] [BIO/CT/24/000036]	M/s Biological E. Ltd.	In light of recommendation of SEC-Vaccine meeting dated 25.06.2024, firm presented the report of Phase I clinical trial of Typhoid and Paratyphoid A Bivalent Vaccine conducted in Europe along with revised Phase I/II clinical trial protocol titled "A prospective multicentre, observer blind, Phase I/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." The committee reviewed the safety report of Phase I clinical trial conducted in Europe. After detailed deliberation, the committee recommended that the firm should submit revised protocol for conduct of Phase I clinical trial in India to CDSCO for further deliberation.
7	Respiratory Syncytial Virus (RSV) and Human Metapneumovirus (hMPV) Virus Like Particle (VLP) Vaccine [Phase III Clinical trial protocol] [GCT/CT04/FF/2024/45221]	IQVIA RDS (India) Private Limited	The proposal was deferred as requested by firm.

8	VAC52416 (JNJ-78901563 [ExPEC9V] [GCT/PostAppr/2024/34944] [CT/14/23-DCG (I)]	M/s. Pharmaceutical Research Associates India Pvt Ltd	The firm presented its proposal for protocol amendment 8 dated 09 August 2024, protocol no. VAC52416BAC3001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.