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 31.07.2024 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 31.07.2024 and recommended the following:

Sr. No.	Name of Vaccine &File no.	Name of Firm	Recommendations
1	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 20 valent [BIO/IMP/24/000060]	M/s Pfizer Limited, Mumbai	The firm presented the Phase III clinical trial report of 20 valent Pneumococcal Conjugate Vaccine (20vPnC) of study titled " A Phase III, single-arm, multicenter trial to describe the safety and immunogenicity of a 20 valent Pneumococcal Conjugate Vaccine in Pneumococcal vaccine-naïve adults ≥18 years of age in India''. After detailed deliberation, the committee recommended that firm should submit the global immunogenicity data of all subjects vis-à-vis immunogenicity data of Indian subjects and the immunogenicity data of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P., 13 valent of Indian subjects for further deliberation.
2	Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried) BIO/CT/24/000070	M/s Serum Institute of India Pvt. Ltd., Pune	The firm presented the Phase III clinical trial report of Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried) of study titled "A Phase III, randomized, double-blind, controlled, multi-center study to compare immunogenicity and safety of SIIPL Meningococcal ACYWX Conjugate Vaccine (NmCV-5) with that of licensed Meningococcal ACWY Vaccine Menactra® in healthy Indian children of 9 months to 17 years of age''.

			After detailed deliberation, the committee recommended for approval to conduct the Phase-III clinical trial as per the presented protocol with the condition to include more sites covering all geographical areas.
3	Rabies Human Monoclonal Antibody (Rabishield) and Rabivax-S [BIO/CT/18/000091] (BIO/PostAppr/2024/33442)	M/s Serum Institute of India Pvt. Ltd., Pune	The proposal was deferred as per the request of firm.
4	Measles and Rubella Vaccine (Live) I.P. (Freeze Dried) [BIO/CT/24/000048]	M/s Zydus Lifesciences Limited	The firm presented the Phase IV clinical trial protocol of Measles and Rubella Vaccine (Live) I.P. (Freeze Dried) titled "A prospective, randomized, parallel, single-blind, four-arm, active-controlled, multicentre, Phase IV clinical trial to evaluate the immunogenicity and safety of Measles and Rubella Vaccine(Live) I.P. compared to Measles and Rubella vaccine (Live) I.P. (Freeze Dried) of M/s Serum Institute of India Pvt. Ltd. and to evaluate lot-to-lot consistency of Measles and Rubella vaccine (Live) I.P. (Freeze dried)of M/s Zydus Life sciences Ltd. in healthy infants aged 9-12 months. After detailed deliberation, the committee recommended for approval to conduct the Phase-IV clinical trial as per the presented protocol.
5	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14-valent) [PCV-14] (Study code: BECT081), CT Permission	M/s Biological E - Shameerpet ,18/1 And 3 ,Azamabad, Hyderabad	The firm presented the amended Phase IV clinical trial protocol of study titled "A prospective multicentre Phase- IV study to evaluate the safety of Biological E's 14 -valent pneumococcal

	No: CT-08/2023 -Biological E. Limited [BIO/CT/23/000065] (BIO/PostAppr/2024/33618)		polysaccharide conjugate vaccine when administered in 6-10-14 weeks dosing schedule to 6-8 weeks old healthy Indian infants." After detailed deliberation, the committee recommended to revise the protocol for increasing sample size for immunogenicity analysis for booster dose. Accordingly, firm should submit revised protocol for further deliberation.
6	Recombinant Rabies G Protein Vaccine [BIO/CT/22/000088] (BIO/PostAppr/2024/32793)	M/s Cadila Pharmaceuticals Limited	The firm presented the Post Marketing Surveillance Report for Recombinant Rabies G Protein Vaccine of study titled “An Active Post Marketing Surveillance to evaluate the safety of Recombinant Rabies G protein vaccine administered in patients with post animal exposure in India. After detailed deliberation, the committee noted the results of the PMS study.
7	Human Papillomavirus 9-valent Recombinant Vaccine (Serotypes 6, 11, 16, 18, 31, 33, 45, 52 and 58) 12-89/MSD/PAC-HPV/23-BD	M/s MSD Pharmaceuticals Pvt. Ltd.,	Firm presented its proposal for update of prescribing information (PI) of the Human Papillomavirus 9-valent Recombinant Vaccine (Serotypes 6, 11, 16, 18, 31, 33, 45, 52 and 58) After detailed deliberation, the committee recommended for updation of PI in line wih EU SmPC