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 27.02.2024 (through web-conferencing)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 27.02.2024 and recommended the following:

Sr. No.	Name of Vaccine & File no.	Name of Firm	Recommendations
1	Respiratory Syncytial Virus (RSV) vaccine(Recombinant Adjuvanted) [Phase – III clinical trial protocol] [BIO/CT/23/000155]	M/s GlaxoSmithKline Pharmaceuticals Limited (GSK)	The firm presented the Phase III clinical trial protocol titled "A Phase III randomized, placebo-controlled, observer blind study in India to evaluate immune response, reactogenicity and safety of a single intramuscular dose of RSVPreF3 OA investigational vaccine when administered to older adults ≥60 years of age and adults 50-59 years of age at increased risk of respiratory syncytial virus lower respiratory tract disease of Respiratory Syncytial Virus (RSV) vaccine (Recombinant Adjuvanted). After detailed deliberation, the committee noted that the proposed study design is descriptive and not based on statistical analysis with number of subjects too low for prospective population of cohort 1 older adults ≥60 years of age & cohort II adults 50-59 years of age with various co-morbidities. Further, the vaccine is not yet approved in any other country in the proposed age group of 50-59 years. In view of above, the committee recommended 1) To submit revised clinical trial protocol with increased sample size for both cohorts of more than 60 years and 50-59 years. 2) To submit detailed clinical study report for the age group 50-59 years from all the clinical trials conducted globally and current regulatory status. 3) To include more clinical trial sites from southern part of India in the

			revised clinical trial protocol.
2	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA) and Haemophilus influenzae type b conjugate vaccine (adsorbed) I.P. (Brand Name: My Five^{TM}) [Phase – II / III Clinical trial protocol] [BIO/CT/23/000146]	M/s Panacea Biotec Ltd	The proposal was deferred as per the request of the firm.
3	10 Valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) [Phase IV clinical trial report] [BIO/CT/22/000063]	M/s Serum Institute of India Pvt. Ltd.	The firm presented the Phase IV clinical trial report titled “A Phase IV, cross-sectional study to evaluate the Pneumococcal Nasopharyngeal Carriage in healthy toddlers following vaccination with 10-Valent Pneumococcal Conjugate Vaccine (PNEUMOSIL®) as part of Universal Immunization Program in India as compared to non vaccinated toddlers. After detailed deliberation, the committee noted the results of Phase IV clinical trial.
4	Measles Vaccine Live, Attenuated (Freeze Dried 10 dose) [Amendment in MA] [12-27/SIIPL/PAC-Measles/23-BD & BIO/MA/24/000004]	M/s. Serum Institute of India Pvt. Ltd.	The firm presented the amendment in manufacturing permission of Measles Vaccine Live, Attenuated (Freeze Dried) (10 dose) due to change in composition of vaccine with respect to quantities of inactive ingredients due to change in fill volume. After detailed deliberation, the committee recommended for approval of amendment in manufacturing permission for change in composition of vaccine

			with respect to quantities of inactive ingredients.
5	Measles and Rubella Vaccine (Live) I.P. (Freeze Dried) [Amendment in MA] [BIO/MA/24/000020]	M/s. Serum Institute of India Pvt. Ltd.	The firm presented the amendment in manufacturing permission of Measles and Rubella Vaccine live attenuated (freeze dried) (10 dose) due to change in composition of vaccine with respect to quantities of inactive ingredients due to change in fill volume. After detailed deliberation, the committee recommended for approval of amendment in manufacturing permission for change in composition of vaccine with respect to quantities of inactive ingredients.
6	Measles and Rubella Vaccine (Live) I.P. (Freeze Dried)- Multi dose Vial (2.5 ml-5 dose) [Amendment in MA] [BIO/MA/23/000136]	M/s Zydus Lifesciences Limited	The firm presented the amendment in manufacturing permission of Measles and Rubella Vaccine (live) I.P. (freeze dried) - multi dose vial (2.5 ml-5 dose) due to change in composition of vaccine with respect to quantities of inactive ingredients due to change in fill volume. After detailed deliberation, the committee recommended for approval of amendment in manufacturing permission for change in composition of vaccine with respect to quantities of inactive ingredients subject to recommendations from CDL,Kasauli.
7	Measles, Mumps and Rubella Vaccine (Live) I.P. (Freeze Dried)- Multi dose Vial (5.0 ml - 10 dose) [Amendment in MA]	M/s Zydus Lifesciences Limited	The firm has presented the amendment in manufacturing permission of Measles, Mumps and Rubella Vaccine (Live) I.P. (freeze dried) - multi dose vial (5.0 ml - 10

	[BIO/MA/24/000003]		dose) due to change in composition of vaccine with respect to quantities of inactive ingredients due to change in fill volume. After detailed deliberation, the committee recommended for approval of amendment in manufacturing permission for change in composition of vaccine with respect to quantities of inactive ingredients subject to recommendations from CDL,Kasauli.