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 03.03.2022 (through web-conferencing)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 03.03.2022 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	BIO/IMP/22/000003 Meningococcal group B Vaccine (r-DNA) component, Adsorbed) MA with Phase IV trial	M/s GSK Pharma India Private Ltd.	Firm presented its proposal for grant of permission to import and market Meningococcal group B Vaccine (rDNA, component, adsorbed) with local clinical trial waiver before the committee. The committee noted that the firm has not submitted any safety and immunogenicity data in Indian Population, the dose schedule proposed by the firm does not correspond to immunization schedule in India for this age group and has also not submitted the prevalence data of Meningococcal B serotype in the country. After detailed deliberation, the committee did not recommend for grant of marketing authorization with local Phase III clinical trial waiver.
2	BIO/CT/21/000169 Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent) CT	M/s Cadila Healthcare Ltd.	Firm presented its proposal for conduct of Phase III clinical trial of Inactivated Influenza Vaccine (Split Virion) I.P. (Tetravalent) (for 0.5ml dose) in the age group of 6 to 35 months. After detailed deliberation, the committee recommended for grant of approval for conduct of proposed Phase III clinical trial as per the protocol presented.
3	BIO/IMP/20/000066 Quadrivalent Inactivated Influenza vaccine (Split Virion) MA	M/s Sanofi Healthcare India Pvt. Ltd.	In light of the recommendation of the Committee in the SEC meeting dated: 10.02.2021, firm presented its proposal for grant of market authorization for Quadrivalent Inactivated Influenza Vaccine (split virion) I.P. (for 0.5ml dose) in the age group of 6 to 35 months with protocol for observational Post Marketing Surveillance study. After detailed deliberation, the committee recommended for grant of market authorization for Quadrivalent Inactivated Influenza Vaccine (split virion) I.P. (for 0.5ml dose) in the age group of 6 to 35

			months with condition to conduct observational Post Marketing Surveillance study as per the protocol presented before the Committee.
4	BIO/CT21/BO/2021/28406 Tetanus Toxoid vaccine MA	M/s Seasons Biologicals Ltd.	Firm presented its proposal for grant of permission to manufacture Tetanus vaccine (adsorbed) IP along with Phase II/III clinical trial report of Tetanus vaccine (adsorbed) IP After detailed deliberation, the committee recommended for grant permission to manufacture Tetanus vaccine (adsorbed) IP.
5	BIO/CT/21/000159 13 Valent PCV Vaccine CT	M/s Pfizer Ltd.	Firm presented its proposal for conduct of Phase IV clinical trial of 13-valent Pneumococcal Conjugate Vaccine in the age group of 18 to 49 years. After detailed deliberation, the committee recommended for grant of approval for conduct of proposed Phase IV clinical trial.
7	BIO/CT/20/000180 Live Attenuated Tetravalent Recombinant Dengue Vaccine CT	M/s Indian Immunological Ltd.	Firm presented its proposal to conduct Phase I clinical trial of Live Attenuated Tetravalent Recombinant Dengue Vaccine in both seronegative and sero positive subjects, along with animal toxicity data before the committee. The committee noted that another Dengue vaccine has been observed to enhance antibody dependent dengue infection in seronegative subjects. After detailed deliberation, the committee recommended for submitting published literature on the long term safety follow up of both seropositive and seronegative subjects who have participated in other clinical trials of dengue vaccine for further evaluation by the committee.