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 29.08.2022 (through web-conferencing)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 29.08.2022 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
01	Typhoid Vi conjugate vaccine MA [Additional indication (45 to 65 years]) [BIO/MA/22/000038]	M/s Zydus Lifesciences Limited	Firm presented its proposal for grant of permission for the additional indication of Typhoid Vi conjugate vaccine for age group 45-65 years along with the Phase III clinical trial report. After detailed deliberation the committee recommended for amendment of indication of Typhoid Vi conjugate vaccine to include the age group of 45-65 years for single dose only.
02	Live Attenuated Tetravalent Recombinant Dengue Vaccine CT [Phase I] [BIO/CT/20/000180]	M/s Indian Immunological Limited	In light of recommendation of SEC meeting dated 03.03.2022, firm presented various published literature of studies on the long term safety follow up of both seronegative and seropositive subjects who have participated in other clinical trials of dengue vaccine for its proposal for grant of permission to conduct Phase I clinical trial of Live Attenuated Tetravalent Recombinant Dengue Vaccine. After detailed deliberation, the committee recommended for grant of permission to conduct proposed Phase I clinical trial.
03	Diphtheria, tetanus and pertussis (acellular, component) vaccine (adsorbed, reduced antigen(s) content) Tdap Vaccine MA[Phase II/III report] [BIO/MA/22/000044]	M/s Serum Institute of India Pvt., Limited	Firm presented its proposal for grant of permission to manufacture Diphtheria, Tetanus and Pertussis (Acellular, Component) vaccine (adsorbed, reduced antigen(s) content) Tdap Vaccine along with Phase II/III clinical trial report, DSMB recommendations, Prescribing information (PI) and Summary of product characteristics (SmPC).

			After detailed deliberation, the committee recommended for grant of permission to manufacture Tdap Vaccine for the age group of 4-65 years. Accordingly, firm should submit revised SmPC & PI. Also, indication for pregnant women to be excluded from SmPC & PI.
04	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-Valent) [CT Phase IV] [BIO/CT/22/000063]	M/s Serum Institute of India Pvt., Limited	The proposal was deferred as per the request of the firm.
05	Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried) MA [BIO/CT21/FF/2022/32551]	M/s Serum Institute of India Pvt., Limited	Firm presented its proposal for grant of permission to manufacture Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried) along with Phase II/III clinical trial report. After detailed deliberation, the committee recommended for grant of permission to manufacture Meningococcal (A, C, Y, W, X) Polysaccharide Conjugate Vaccine (Freeze-Dried) [single dose & five dose] for age group 18-85 years.
06	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-Valent) MA [2+1 Schedule] [BIO/MA/22/000027]	M/s Serum Institute of India Pvt., Limited	Firm presented its proposal for grant of permission for additional indication of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-Valent) for dose schedule of 2+1 (6 weeks, 14 weeks & 9 Months) along with Phase-III clinical trial report. The committee noted that the vaccine is approved with dose schedule of 3+0 schedule. After detailed deliberation, the committee recommended for grant of permission for additional indication of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-Valent) with dose schedule of in 2+1(6 weeks, 14 weeks & 9 Months).

07	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-valent) BIO/MA/20/000001	M/s Serum Institute of India Pvt., Limited	The proposal was deferred as per the request of the firm.
08	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) [2+1 schedule] With 2-PE preservative [CT Phase III] [BIO/CT/20/000072]	M/s Biological E Limited,	In light of recommendation of SEC meeting dated 26.04.2022, firm presented complete safety data of Phase III trial of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) (Multi dose presentation with preservative) in 3+0 schedule. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial with dose schedule of 2+1(6 weeks, 14 weeks & 9 Months).
09	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14-Valent) MA [3+0 Schedule] [BIO/MA/22/00008]	M/s Biological E Limited,	Firm presented its proposal for grant of permission to manufacture Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) Single dose (without preservative) & Multi dose (with preservative) with dose schedule of 3+0 (6, 10, 14 weeks of age) along with the Phase III clinical trials reports [Single dose (without preservative) & Multi dose (with preservative). After detailed deliberation, the committee recommended for grant of permission to manufacture Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14-Valent) Single dose (without preservative) & Multi dose (with preservative) with dose schedule of 3+0 (6, 10, 14 weeks of age). * Dr. Savita Verma didn't participate in the deliberation of the clinical trial report with single dose.
10	Tetanus toxoid, reduced diphtheria toxoid,	M/s Abbott India Limited	The proposal was deferred as per the request of the firm.

	recombinant pertussis vaccine [CT Phase III] [BIO/CT/22/000045]		
11	20-valent Pneumococcal Conjugate Vaccine [CTPhase III] [BIO/CT/22/000051]	M/s Pfizer Limited	Firm presented its proposal for grant of permission to conduct Phase III clinical trial of Pneumococcal Polysaccharide Conjugate Vaccine (20 Valent). After detailed deliberation, the committee recommended that the firm should submit the justification for following: 1. Sample size calculation for immunogenicity along with statistical power. 2. Subset population for determination of OPA titres. Accordingly, the firm should submit their reply for further deliberation before the committee.

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