

**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 26.04.2022 (through web-conferencing)**

**The Recommendations:**

The SEC (Vaccine) deliberated the proposals on 26.04.2022 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	BIO/MA/22/000029  Recombinant BCG (r-BCG) Vaccine  MA	M/s Serum Inst. of India Pvt., Ltd.	<p>Firm presented its proposal for grant of emergency use authorization for rBCG vaccine (VPM1002) for prevention of Tuberculosis in <math>\geq 6</math> years of age before the committee.</p> <p>The firm presented Phase-IIa &amp; IIb clinical data in infants carried out at South Africa for prevention of TB in infants. A Phase II/III trial with the objective of Prevention of recurrence of TB in 2000 adult participants is ongoing.</p> <p>The firm also stated that Phase III clinical trial of rBCG vaccine being conducted by ICMR in 12000 participants of age <math>\geq 6</math> years healthy household contacts in the country is ongoing &amp; ICMR is yet to submit the clinical trial data.</p> <p>The committee noted that, the firm has requested for emergency use authorization for rBCG vaccine in age group age <math>\geq 6</math> years of age for prevention of TB in children based on the Phase IIb trial conducted in Africa and firm has not conducted local clinical trial in proposed age group and indication in the country.</p> <p>After detailed deliberation, the committee recommended that firm should submit safety and immunogenicity data in proposed indication &amp; age group for consideration of its proposal.</p>
2	BIO/CT/22/000019  Typhoid Conjugate Vaccine (Bivalent) Typhoid Fever and Paratyphoid A Fever  CT (Phase I)	M/s Serum Inst. of India Pvt., Ltd.	<p>Firm presented its proposal for grant of permission for conduct of Phase I clinical trial of Typhoid &amp; Paratyphoid A vaccine (Bivalent) in adult population along with the pre-clinical study data before the committee.</p> <p>After detailed deliberation, the committee</p>

**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 26.04.2022 (through web-conferencing)**

			recommended for grant of permission to conduct proposed Phase-I clinical trial.
3	BIO/IMP/22/000002  Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Inactivated Poliomyelitis Vaccine I.P.  MA (CT waiver)	M/s GSK Pharmaceuticals Pvt. Ltd.	Firm presented its proposal for grant of permission to import INFANRIX-IPV in the country without conducting local clinical trial.  After detailed deliberation, the committee recommended to generate the safety and immunogenicity data on Indian population for consideration of marketing authorization.
4	BIO/MA/22/000108  Inactivated Hepatitis A Vaccine (Adsorbed) I.P.  MA	M/s Human Biologicals Institute Ltd.	Firm presented its proposal for grant of permission to manufacture Inactivated Hepatitis A Vaccine, IP along with Phase II/III clinical trial data before the committee.  After detailed deliberation, the committee recommended to grant Marketing Authorization to the firm for 0.5 ml dose for children (above 1 year) and adolescents and 1ml in adults (age 19 years to 49 years).
5	BIO/MA/20/000051  Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents (Td Vaccine)  MA	M/s Human Biologicals Institute Ltd.	Firm presented its proposal for grant of permission to manufacture Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents (Td Vaccine) along with phase II/III clinical trial data for trial conducted in adults & adolescents (Age 10 years to 60 years) before the committee.  After detailed deliberation, the committee recommended for grant of marketing authorization permission of Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents (Td Vaccine).
6	BIO/CT/22/000034  Pneumococcal Polysaccharide	M/s Tergene Biotech Private Limited	The firm did not turn up for the presentation.

**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 26.04.2022 (through web-conferencing)**

	Conjugate Vaccine (adsorbed), 15 Valent I.P  CT (Phase III)		
7	BIO/CT/20/000072  Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) [2+1 schedule] With 2-PE preservative  CT (Phase III)	M/s Biological E	In light of the recommendations of SEC meeting dated 06.07.2020, firm presented interim safety data of 7 days post first dose of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) with 2-PE preservative from Phase III clinical trial [3+0 schedule] With 2-PE preservative for its proposal for grant of permission to conduct Phase III clinical trial of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) with 2-PE preservative with 2+1 schedule before the committee.  After detailed deliberation, the committee recommended that firm should submit interim safety data of 4 weeks after three doses, in compliance with the condition of the Clinical trial for further evaluation.
8	BIO/MA/22/000009  Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human)  MA	M/s Biological E Ltd.	Firm presented its proposal for grant of permission for expansion of indication of Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) below 1 year and above 49 years of age without any safety & immunogenicity data in this age group in the Indian population.  After detailed deliberation, the committee recommended to generate and submit safety and immunogenicity data in Indian population in the proposed age group for consideration of proposal.
9	BIO/CT/22/000037  Rabies Vaccine, Human I.P. [Purified Inactivated Vero Cell Rabies vaccine –	M/s Cadila Healthcare Limited	Firm presented its proposal for grant of permission to conduct Phase III Rabies Vaccine, Human I.P. [Purified Inactivated Vero Cell Rabies vaccine – Lyophilized (PVRV)] before the committee.

**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 26.04.2022 (through web-conferencing)**

	Lyophilized (PVRV]  CT (Phase I)		After detailed deliberation, the committee recommended to conduct Phase I clinical trial.
10	SUGAM#30385  20-valent pneumococcal conjugate vaccine (20vPnC)  (GCT)	M/s Pfizer Ltd., India	<p>The applicant presented the proposed phase III study protocol no.: B7471024, final protocol dated 06-Dec-2021 with the Investigational Product-20vPnC/PF-06482077 before the Committee. Taiwan is the other participating country in the proposed trial.</p> <p>After detailed deliberation, the Committee noted that the study protocol can not be considered in the present form. The Committee recommended that the study should be revised to meet the phase III clinical study criteria sufficient to supplement the proposed MA (for pediatric population) in India. Immunogenicity should be primary (or co-primary) objective of the study and for this adequate number of subjects with proper statistical analysis to be included and the non-inferiority criteria (with comparator arm) should also be defined in the study protocol.</p>
11	12-20/MSD/PAC-HPV-9v/22-BD  Human Papillomavirus 9-valent (Recombinant) Vaccine  PAC	M/s MSD Pharmaceuticals Pvt. Ltd.	<p>Firm presented its proposal for alternate two dose regimen of Human Papillomavirus 9-valent (Recombinant) Vaccine before the committee with waiver of local Phase-III and Phase-IV clinical trial.</p> <p>After detailed deliberation, the committee did not recommend the proposal at this stage.</p>
12	SUGAM#30357  Staphylococcus (S.) aureus vaccine (Sa-5Ag adjuvanted vaccine)	M/s GSK Pharmaceuticals Ltd.	The applicant presented the proposed phase I/II study protocol no.:208833, Amendment 4 dated 30-Nov-2021 with the Investigational Product-S. aureus vaccine with AS01E adjuvant before the Committee. The committee noted that the

**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 26.04.2022 (through web-conferencing)**

	(GCT)		applicant wishes to only perform the Part II (i.e. Phase II as proof of principle) of the study in India and no blood sampling will be done for cell mediated immune (CMI) response in the country. After detailed deliberation, the committee recommended to conduct the proposed study as per the protocol.
--	-------	--	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------