

**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 24.01.2023 (through web-conferencing)**

**The Recommendations:**

The SEC (Vaccine) deliberated the proposals on 24.01.2023 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	Dengue Tetravalent Vaccine (live attenuated) Type: Phase III CT File no. BIO/CT/22/000121	M/s. Takeda Pharmaceutical India	<p>Firm presented its proposal for grant of permission to conduct Phase III clinical trial of Dengue Tetravalent Vaccine (live attenuated) containing DEN1: <math>\geq 3.3 \log_{10}</math> PFU/dose, DEN2: <math>\geq 2.7 \log_{10}</math> PFU/dose, DEN3: <math>\geq 4.0 \log_{10}</math> PFU/dose, DEN4: <math>\geq 4.5 \log_{10}</math> PFU/dose of 0.5 mL.</p> <p>The committee noted that the vaccine is approved for marketing in Indonesia, European Medicines Agency (EMA) for the prevention of dengue disease in individuals from 4 years of age. The efficacy of Dengue vaccine in providing protection against dengue infection is currently being evaluated in a Phase 3 trials in many countries.</p> <p>After detailed deliberation, the committee recommended that the firm should revise the phase III clinical trial protocol as below:</p> <ol style="list-style-type: none"> <li>1. Efficacy should be included as an objective of the trial and sample size should be revised accordingly.</li> <li>2. Blood withdrawal should be removed at Visit 3 (Day 30).</li> <li>3. Constitution of DSMB members should be included for monitoring of the study at regular intervals</li> </ol> <p>The firm should submit revised protocol for further deliberation</p>

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			before the committee.
2	Tetravalent Dengue vaccine Type: Phase III CT File No. BIO/CT/22/000117	M/s Panacea Biotec Limited	In light of the recommendation of SEC (vaccine) meeting dated 21.09.2021, firm presented its proposal for grant of permission to conduct Phase III clinical trial of Tetravalent Dengue vaccine containing DEN1: NLT 3.0 log <sub>10</sub> PFU/dose, DEN2: NLT 3.0 log <sub>10</sub> PFU/dose, DEN3: NLT3.0 log <sub>10</sub> PFU/dose, DEN4: NLT 3.0 log <sub>10</sub> PFU/dose of 0.5 ml. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial as per the presented protocol.  *Dr. Savita Verma did not participate in the deliberation.
3	Recombinant Rabies G Protein Vaccine Type: Phase III (re-deliberation) File no. BIO/CT/22/000088	M/s Cadila Pharmaceuticals Limited	In light of the recommendation of SEC meeting dated 21.11.2022, firm presented its proposal for grant of permission to conduct Phase III clinical trial of Recombinant Rabies G Protein Vaccine in pediatric population in the age group of 1 year to <18 years.  After detailed deliberation, the committee recommended for grant of permission for conduct of Phase III clinical trial as per presented revised protocol.
4	Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV) Type: Phase I CT (re-deliberation) File no. BIO/CT/22/000107	M/s Biological E. Limited	In light of the recommendations of SEC meeting dated 21.12.2022, firm presented its proposal for grant of permission to conduct Phase I clinical trial of Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV).

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			After detailed deliberation, the committee recommended for grant of permission for conduct of Phase I clinical trial as per the presented revised protocol.
5	Tetanus toxoid, reduced diphtheria toxoid, reduced recombinant pertussis vaccine Type: Phase III CT File no. BIO/CT/22/000154	M/s TechInvention Lifecare Pvt Ltd	Firm presented its proposal for grant of permission to conduct Phase III clinical trial of Tetanus toxoid, reduced diphtheria toxoid, reduced recombinant pertussis vaccine. The committee noted that the vaccines is already approved and marketed in Thailand, Singapore and Phase III clinical trials are ongoing in Australia and Switzerland.  After detailed deliberation, the committee recommended for grant of permission to conduct Phase III of clinical trial as per presented protocol.
6	Herpes Zoster Vaccine (Recombinant) Adjuvanted) Type: Phase III CT File no. BIO/IMP/20/000041	M/s GSK Pharmaceuticals Limited	Firm presented interim safety report of Herpes Zoster Vaccine (Recombinant) Adjuvanted) of Phase III clinical trial as a part of condition of import and marketing permission granted by this office.  After detailed deliberation, the committee noted the results of the interim safety report.
7	Purified Chick Embryo Cell Rabies Vaccine (ChiroRab)  Type: PMS study File no. 12-01/Chiron/2023-BD	M/s Chiron Behring Vaccine Private Limited	Firm presented its proposal for grant of permission to conduct Post marketing surveillance study of Purified Chick Embryo Cell Rabies Vaccine (ChiroRab) for pre and post exposure prophylaxis.  After detailed deliberation, the committee recommended for conduct

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			of PMS study as per presented protocol.
8	Inactivated Influenza Vaccine (Surface Antigen) I.P. 0.5 ml PFS Type: PAC File no. 12-117/Abott/PAC-Influvac/16-BD	M/s Abbott India Limited	Firm presented updated package insert of Inactivated Influenza Vaccine (Surface Antigen) I.P. 0.5 ml PFS. After detailed deliberation, the committee recommended for the updation of the package insert in line with approval of EU SmPC, changes approved in the country of origin (The Netherlands) and New Drugs & Clinical Trials Rules, 2019.
9	Inactivated Influenza Vaccine (Surface Antigen) I.P. (Quadrivalent) 0.5 ml PFS Type: PAC File no. 12-117/Abott/PAC-Influvac/16-BD	M/s Abbott India Limited	Firm presented updated package insert of Inactivated Influenza Vaccine (Surface Antigen) I.P. (Quadrivalent) 0.5 ml PFS. After detailed deliberation, the committee recommended for the updation of the package insert in line with approval of EU SmPC, changes approved in the country of origin (The Netherlands) and New Drugs & Clinical Trials Rules, 2019.
10	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. 13 valent [Prevenar 13] Type: PAC File no. 12-70/Pfizer/PAC-Prevenar 13/22-BD	M/s Pfizer Limited	Firm presented updated package insert of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. 13 valent [Prevenar 13]. After detailed deliberation, the committee recommended for updation of package insert in line with EU SmPC and New Drugs & Clinical Trials Rules, 2019.
11	Human Papillomavirus 9-Valent (Recombinant) Vaccine	M/s Pharmaceuticals Pvt. MSD	Proposal is deferred as per the firm's request.

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	Type: PAC File no. 12-30/MSD/PAC-HPV/21-BD	Limited	
12	Human Papillomavirus 9-Valent (Recombinant) Vaccine (serotypes 6,11,16,18, 31, 45, 52 & 58) Type: PAC File no. 12-30/MSD/PAC-HPV/21-BD	M/s MSD Pharmaceuticals Pvt. Limited	