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 25.02.2025 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 25.02.2025 and recommended the following:

Sr. No.	Name of Vaccine & File no.	Name of Firm	Recommendations
1	Recombinant BCG Vaccine, VPM1002 & Immuvac (heat killed suspension of Mycobacterium w). [Phase-III CT Report] [BIO/CT/18/000057] & [BIO/PostAppr/2025/36816]	India TB Research Consortium, India Council of Medical Research (ICMR)	The firm presented Phase III clinical trial report of study titled, "A Phase III, randomized, double-bind, three arm placebo controlled trial to evaluate the efficacy and safety of two vaccines VPM1002 and Immuvac (Mw) in preventing tuberculosis (TB) in healthy household contacts of newly diagnosed sputum positive pulmonary TB patients." After detailed deliberation, the committee noted the results of the study with the following observations: - 1. During presentation, the applicant has shown post -hoc analysis data including additional subgroup (6 to < 10 years). 2. Applicant was advised to infer efficacy by comparing values for cytokines etc. between test group with placebo group for drawing conclusions. Prof. (Dr) Urvashi B Singh, DDG (TB) & Dr Sanjay Kumar Mattoo, Joint Commissioner (SAG officer) Central TB Division, National TB Elimination Program Division, MoHFW, Govt of India participated as special invitees.
2	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), inactivated Poliomyelitis and Haemophilus influenzae Type	M/s Biological E. Limited, Hyderabad	The firm presented Phase III clinical trial protocol, titled, "A prospective, single blind, randomised, active controlled Phase-III study to assess the

	b Conjugate Vaccine (Adsorbed) [Phase III study protocol along with Phase II CT Report] [BIO/CT/25/000002]		immunogenicity and safety of Biological E's Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV) in 6-8 weeks old healthy infants in a 6-10-14 weeks dosing schedule along with report of Phase II clinical trial conducted in the country. The committee noted the results of Phase II clinical trial report. After detailed deliberation, the committee recommended for conduct of the Phase III clinical trial as per the presented protocol. (Dr. Savita Verma didn't participate in deliberation)
3.	Varicella Vaccine Live I.P. [Phase III CT Protocol along with study report of Phase I/III CT conducted in China] [BIO/CT/24/000161]	M/s G. C. Chemie Pharmie Ltd., Mumbai	The firm presented Phase III clinical trial protocol titled "A prospective, randomized, observer blind, parallel, active controlled, multicenter, non-inferiority Phase III study to evaluate the immunogenicity and safety of Varicella Vaccine, Live in healthy subjects" along with report of Phase I/III clinical trials conducted in China. The committee noted that the vaccine is approved in China in the age group of 1 – 12 years as single dose based on the Phase I/III comparative clinical trial with already approved vaccine in China. After detailed deliberation, the committee recommended that the firm should submit following justification: - 1. Composition of test vaccine vis-à-vis reference vaccine proposed to be used in the

			Phase III clinical trial after reconstitution and comparison of the composition of the test vaccine with the vaccine used in the Phase I/III clinical trial and subsequently approved in China. 2. Rationale / justification for two doses of vaccine in 1 – 12 years while single dose vaccine is approved for the same age group in the country of origin. 3. The interval of two doses proposed in the clinical trial protocol is different from the clinical study conducted in Chinese population. 4. Reference for selection of sero-conversion rate as Varicella IgG antibody level > 125 IU/L in the immunogenicity analysis. 5. Total doses administered in real world scenario with demographic characteristics. 6. Justification for conducting study in single centre in China & not in different parts of the country. 7. Regulatory status of the applied product in other developed countries.
4.	Typhoid Vi Conjugate Vaccine (Typbar TCV®) [Phase III CT Protocol (Amendment)]	M/s Bharat Biotech International Ltd., Hyderabad	The firm presented amendment in Phase III clinical trial protocol titled, “A Phase III open label study to evaluate the immunogenicity and safety of purified Vi capsular polysaccharide (of Salmonella

	[BIO/CT/23/000112] [BIO/Post Appr/2024/36335]		typhi, Ty2 strain) tetanus toxoid conjugate vaccine; Typbar TCV® in Adults (>65 Years). After detailed deliberation, the committee recommended for approval of amended Phase III clinical trial protocol as presented by the firm. (Dr. Savita Verma didn't participate in deliberation)
5.	Quadrivalent Influenza Vaccine (Fluarix Tetra) [Phase IV CT report] [BIO/CT/22/000085] [BIO/Post Appr/2024/36090]	M/s IQVIA RDS (India) Pvt Ltd.	The firm presented Phase IV clinical trial report titled "A single-arm, open-label, multi-center, Phase IV trial to evaluate the reactogenicity, safety, and immunogenicity of Quadrivalent seasonal influenza vaccine (Fluarix Tetra) in participants aged 65 years and older in India". After detailed deliberation, the committee noted the results of the study.
6.	Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Inactivated Poliomyelitis Vaccine I.P. (Tetraxim) [Additional Indication] [BIO/IMP/24/000127]	M/s Sanofi Healthcare India Private Ltd.	The proposal was deferred as per request of the firm.
7.	Tetanus Toxoid, Reduced Diphtheria Toxoid & Acellular Pertussis Vaccine Adsorbed (Adacel®) [PI Update] [12-168/Sanofi/PAC-Many Vac/16-BD (I)]	M/s Sanofi Healthcare India Private Limited	In light of the recommendations of SEC dated 22.08.2024, the firm presented global data in support of proposed changes. After detailed deliberation, the committee recommended for updation of PI in line with EU SmPC.

8.	Varicella Vaccine, Live I.P. [PI Update] [12-75/MSD/PAC-Varicella Vaccine/14-BD	M/s MSD Pharmaceutical Private Limited	Firm presented its proposal for updation of prescribing information for Varicella Vaccine, Live IP. After detailed deliberation, the committee recommended for updation of PI in line with EU SmPC.