

**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 27.06.2023 (through web-conferencing)**

**The Recommendations:**

The SEC (Vaccine) deliberated the proposals on 27.06.2023 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	DTPa-IPV-Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Inactivated Poliomyelitis vaccine [Phase III CT] [BIO/CT/23/000037]	M/s IQVIA RDS (India) Private Limited	Firm presented the proposal for grant of permission to conduct Phase III clinical trial for DTPa-IPV - Adsorbed Diphtheria, Tetanus, Pertussis (Acellular Component) and Inactivated Poliomyelitis vaccine. After detailed deliberation, the committee recommended that the firm should submit the revised Phase III clinical trial protocol: <ol style="list-style-type: none"> <li>1. Including approved comparator arm. Accordingly, sample size should be calculated statistically.</li> <li>2. Window period for visit 2 should be from 28days to 48days for immunogenicity study.</li> </ol> Accordingly, the firm should submit revised Phase III clinical trial protocol for further deliberation.
2	Recombinant Hepatitis E Vaccine (E. Coli) [MA] [BIO/IMP/23/000032]	M/s Urihk Pharmaceutical Private Limited	Firm presented the proposal for grant of permission to import and market of Recombinant Hepatitis E Vaccine (E. Coli) along with Phase III clinical trial report. After detailed deliberation, the committee recommended that firm should submit the following: <ol style="list-style-type: none"> <li>1. Evidence of correlation of protection of Recombinant Hepatitis E Vaccine (E. Coli) along with published report.</li> <li>2. Published Clinical trial data conducted in other countries.</li> </ol>

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			Further, the committee recommended to conduct inspection of the clinical trial sites.
3	HPV vaccine (PMS) [BIO/CT/23/000055]	M/s Serum Inst. of India Private Limited	<p>Firm presented its proposal for grant of permission to conduct Phase IV/PMS study of HPV vaccine titled "A single-arm, multicentric, post-marketing surveillance study to assess the safety of SIIPL's qHPV vaccine (CERVAVAC™) when administered in at two-dose schedule to girls and boys aged 9-14 years and in a three-dose schedule to women and men aged 15-26 years".</p> <p>After detailed deliberation, the committee recommended for conduct of Phase IV clinical trial of HPV vaccine as per the presented protocol.</p> <p>Accordingly, the firm is required to revise the title and submit revised protocol to CDSCO.</p>
4	Inactivated Salk Polio Vaccine (Adsorbed) [CT [Phase –II/III Interim Report] [BIO/CT/21/000057]	M/s Serum Inst. of India Private Limited	<p>Firm presented the interim report of Phase II clinical trial of the approved Phase II/III clinical trial of Inactivated Salk Polio Vaccine (Adsorbed).</p> <p>After detailed deliberation, the committee noted the interim report of Phase II clinical trial and recommended for further conduct of Phase III clinical trial as per the approved protocol.</p>
5	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent) [Phase IV CT]	M/s Biological E. Limited	Firm presented its proposal for grant of permission for conduct of Phase IV Clinical trial of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14 Valent).

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	[BIO/CT/23/000065]		After detailed deliberation, the committee recommended for grant of permission for conduct of Phase IV clinical trial as per the protocol presented.
6	Hepatitis B Vaccine (rDNA) [PMS Study] [BIO/CT/23/000074]	M/s Biological E. Limited,	<p>Firm presented its proposal for grant of permission to conduct Phase IV/PMS study of Hepatitis B Vaccine (r-DNA) titled "A multicentre single arm, Phase IV, post marketing surveillance study to evaluate the safety of Biological E's monovalent recombinant Hepatitis B vaccine when administered to 6-8 weeks old infants in 6-10-14 weeks dosing schedule".</p> <p>After detailed deliberation, the committee recommended for conduct of PMS study of Hepatitis B Vaccine (rDNA) as per the presented protocol.</p> <p>Accordingly, the firm is required to revise the title and submit revised protocol to CDSCO.</p> <p>*Dr Savita Verma did not participate in the deliberation.</p>
7	Japanese Encephalitis Vaccine, Inactivated (Adsorbed, Human) [Phase IV CT] [BIO/CT/23/000060]	M/s Bharat Biotech International Limited	<p>Firm presented its proposal for grant of permission for conduct of Phase IV clinical trial of Japanese Encephalitis Vaccine, inactivated (Adsorbed, Human) at age group of 1year to more than 50 years.</p> <p>After detailed deliberation, the committee recommended that the firm should design the protocol as Phase III clinical trial for proposed</p>

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			age group. Accordingly, firm is required to submit revised protocol for further deliberation.
8	RSVPreF3 vaccine [GCT Phase III CT] [CT/23/000032]	M/s GSK Pharmaceutical Limited	Firm presented its proposal for grant of permission for conduct of Global Phase III Extension safety follow-up study for trial of RSVPreF3 vaccine with protocol no- 219510 (RSV-MAT-015). After detailed deliberation, the committee recommended for grant of permission to conduct the study.
9	Human Papillomavirus 9-valent recombinant vaccine (serotypes 6,11,16,18,31,33,45,52 and 58) [PAC] [12-30/MSD/PAC-HPV/21-BD]	M/s MSD Pharmaceuticals Private Limited	Firm presented its proposal for package insert update – addition of Gardasil 9 post marketing experience with editorial revisions (CCDS-V503-I-072019). After detailed deliberation, the committee recommended for the proposed PI updates in line with EU SmPC.
10	Human Papillomavirus 9-valent recombinant vaccine (serotypes 6,11,16 and 18) [PAC] [12-58/MSD/PAC- Quadrivalent/17-BD]	M/s MSD Pharmaceuticals Private Limited	Firm presented its proposal for package insert update of Human Papillomavirus Quadrivalent (Serotypes 6, 11, 16 and 18) recombinant vaccine (WPC-V501-I-022015). After detailed deliberation, the committee recommended for the proposed PI updates in line with EU SmPC.