Minutes of the Meeting of Subject Expert Committee (SEC) - Vaccine to review proposals and advice Drugs Controller General (India) in matters for Biologicals held on 15.06.2022 (through web-conferencing)

The Recommendations:
The SEC (Vaccine) deliberated the proposals on 15.06.2022 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1.	BIO/MA/22/000064 Quadrivalent HPV vaccine [MA]	M/s Serum Institute of India Private Limited	Firm presented its proposal for grant of marketing authorization permission of Quadrivalent Human Papilloma Virus Vaccine (Recombinant) (qHPV) along with Phase II/III clinical trial report before the committee. During the meeting, the committee also reviewed the Prescribing information (PI) of the vaccine. After detailed deliberation, the committee recommended for the grant of marketing authorization permission of Quadrivalent Human Papilloma Virus Vaccine (Recombinant) (qHPV) for the age group of 9-14 years, two-doses schedule (0 and 6 months) and for age group of 15-26 years, three-dose schedule (0, 2 and 6 months) with the condition to carry out Post Marketing Surveillance (PMS) study.
2.	BIO/MA/22/000052 Hexavalent vaccine [MA]	M/s Serum Institute of India Private Limited	Firm presented its proposal for grant of marketing authorization permission of Hexavalent (DTwP-HepB-IPV-Hib) Vaccine along with Phase II/III Clinical Trial Report. After detailed deliberation, the committee recommended for grant of marketing authorization permission of Hexavalent (DTwP-HepB-IPV-Hib) Vaccine.
3.	BIO/CT/22/000022 Diphtheria and Tetanus Vaccine (Adsorbed) for Adults and Adolescents, I.P. [Phase II/III CT]	M/s Panacea Biotec Limited	Firm presented its proposal for grant of permission to conduct Phase II/III Clinical Trial of Diphtheria and Tetanus Vaccine (Adsorbed) in Adults and Adolescents age group. After detailed deliberation, the committee recommended for the grant of permission to conduct Phase II/III trial with the condition that firm shall submit safety data of 7 days post vaccination of at least 30 subjects to DSMB & CDSCO, for proceeding to Phase III part of trial. Accordingly, firm shall submit revised phase II/III clinical trial protocol to CDSCO for approval.

4.	BIO/CT/22/000034 Hepatitis B vaccine (rDNA) [Phase IV CT Report]	M/s Biological E Limited	The firm presented Phase IV clinical trial report of Hepatitis B vaccine before the committee. After detailed deliberation, the committee noted the results of phase IV clinical trial report.
5.	BIO/CT/22/000034 Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed), 15 Valent [Phase III CT]	M/s Tergene Biotech Private Limited	Firm presented its proposal for grant of permission to conduct Phase III clinical trial of Pneumococcal Polysaccharide Conjugate Vaccine (adsorbed), 15 Valent I.P. for 2+1 schedule. During the meeting, the firm also presented interim safety data of ongoing Phase III (3+0 Schedule) clinical trial. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III trial with the following conditions: 1. Opsonophagocytic Assay (OPA) titer analysis shall be included and carried out in subset of population. 2. Dropout rate should not be more than 15%. Accordingly, firm shall submit revised Phase III clinical trial protocol to CDSCO for approval.
6.	BIO/CT/22/000006 13-valent Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. [Phase III CT]	M/s G. C. Chemie Pharmie Limited	In continuation to SEC meeting dated 21.02.2022, firm presented its justification for carrying out Opsonophagocytic assay (OPA) titre in 25% subset and not in all subjects. After detailed deliberation, the committee recommended that opsonophagocytic assay (OPA) be conducted in subset population of 25% and rest other conditions of meeting dated 21.02.2022 shall remain the same.

7.	BIO/CT/21/000140 Sabin Inactivated Polio Vaccine (sIPV) [Phase III CT]	M/s Urihk Pharmaceutical Private Limited	Firm presented its proposal to conduct Phase III clinical trial of imported Poliomyelitis Vaccine (Inactivated) IP. After detailed deliberation, the committee recommended that the proposed trial can be carried with following conditions: 1.The firm should conduct type-2 poliovirus antibody assessment also from accredited laboratory. 2. After initial enrollment and vaccination of first 50 infants, the safety report to be submitted and reviewed by DSMB for further continuation of the trial. 3. The DSMB recommendations should be submitted to the CDSCO. Accordingly, firm shall submit the revised protocol to CDSCO for approval.
8.	GCT/PostAppr/2022/16973 RSV Maternal vaccine [GCT Protocol Amendment, Study-RSV-MAT-009]	M/s GSK	Firm presented its proposal for protocol amendment 4.0, dated 15/03/2022 before the committee. The committee noted that the applicant has suspended further enrollment globally due to urgent safety concerns and as per IDMC recommendation. The proposed protocol amendment mainly for safety follow up. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.
9.	GCT/PostAppr/2022/16974 RSV Maternal vaccine [GCT Protocol Amendment, Study-RSV-MAT-012]	M/s GSK	Firm presented its proposal for protocol amendment 1.0, final dated 15/03/2022 before the committee. The committee noted that the applicant has suspended further enrollment globally due to urgent safety concerns and as per IDMC recommendation. The proposed protocol amendment mainly for safety follow up. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.