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 21.02.2023 (through web-conferencing)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 21.02.2023 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	Yellow Fever Vaccine (Live) (I.P) [CT (Phase II/III)] [BIO/CT/23/000002]	M/s Serum Institute of India Pvt., Limited	Firm presented its proposal for grant of permission to conduct Phase II/III clinical trial of Yellow Fever Vaccine (Live) (I.P.) in ≥ 9 months to <18 years of age group along with Phase I clinical trial report. The committee reviewed the Phase-I clinical trial report and recommended that the firm should submit detailed data on protocol deviations which should include 1) No of subjects visited in each study visit in compliance with protocol. 2) Immunization data on Day 28 3) Details of visits and safety follow-up for each subject. 4) Details of each deviation and its evaluation with justification. Further, the firm presented the Phase II/III clinical trial protocol. After detailed deliberation, the committee recommended that the firm should revise the Phase II/III clinical trial protocol as below: 1) Phase II and Phase III design should be separated in the protocol with clear objective & distribution of subjects in both the phases. 2) The safety (solicited adverse events reported) should be assessed for all the subjects enrolled in the clinical trial with diary cards. 3) The number of subjects should be increased with statistically significant sample size. 4) The clinical trial should be stratified and required to be conducted in adult subjects followed by trial in pediatric

			population specifying age group cohorts. *Dr. Savita Verma did not participate in the deliberation.
2	Yellow Fever Vaccine (Live) (I.P) [CT (Phase II/III)] [BIO/CT/22/000153]	M/s Serum Institute of India Pvt., Limited	Firm presented its proposal for grant of permission to conduct Phase II/III clinical trial of Yellow Fever Vaccine (Live) (I.P) in adults aged ≥ 18 years along with Phase I clinical trial report. The committee examined the Phase-I clinical trial report and recommended that the firm should submit detailed data on protocol deviations which should include 1) No of subjects visited in each study visit in compliance with protocol. 2) Immunization data on Day 28 3) Details of visits and safety follow-up for each subject. 4) Details of each deviation and its evaluation with justification. Further, the firm presented the Phase II/III clinical trial protocol. After detailed deliberation, the committee recommended that the firm should revise the Phase II/III clinical trial protocol as below: 1) Phase II and Phase III design should be separated in the protocol with clear objective & distribution of subjects in both the phases. 2) The safety (solicited adverse events reported) should be assessed for all the subjects enrolled in the clinical trial with diary cards. 3) The number of subjects should be increased with statistically significant sample size. *Dr. Savita Verma did not participate in the deliberation.

3	Hepatitis B Vaccine (r-DNA) [PMS Waiver] [12-32/B.E./13-BD]	M/s Biological E Limited	Firm is having manufacturing and marketing permission in Form 46 vide no MF-197/2013 for Hepatitis B Vaccine (r-DNA) IP with condition to conduct the PMS study in 500 subjects. Firm presented its proposal with request for PMS study waiver. After detailed deliberation, the committee recommended that the firm should conduct PMS study in compliance with conditions of manufacturing and marketing permission in Form 46.
4	Diphtheria Anti Toxin (DAT) [PMS] [12-02/Premium/2023-BD]	M/s Premium Serum and Vaccines Pvt. Ltd., Mumbai	Firm presented proposal for conducting PMS study on Diphtheria Anti Toxin (DAT) for Liquid formulation retrospectively and for Lyophilized formulation prospectively. After detailed deliberation, the committee recommended for approval of conducting the PMS study with condition to revise the presented PMS protocol w.r.t. following. 1) The firm should define age group for the study. 2) The firm should take ethics committee approval for waiver of informed consent for retrospective study of liquid formulation. Accordingly, firm should submit revised protocol to CDSCO for further review.
5	Quadrivalent Meningococcal Conjugate Vaccine [GCT Phase III clinical trial] [CT/22/000059]	M/s Sanofi Healthcare Pvt Limited	The firm presented proposal for Protocol number MET55 amendment version 3.0, dated 06 June 2022 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment

			subject to condition that the study should be conducted in statistically significant number of subjects, accordingly the firm should submit revised protocol to CDSCO for further review.
6	Human Papillomavirus 9-valent recombinant vaccine (serotypes 6, 11, 16, 18, 31, 33, 45, 52 and 58) [Post Approval Change] [12-30/MSD/PAC-HPV/21-BD]	M/s MSD Pharmaceutical Pvt.,Limited	The firm submitted its proposal for update of package insert for an alternate 2-dose regime for 9-14 years of age group to the existing approved 3 dose regimen. Earlier, the proposal was deliberated before SEC meeting held on 26.04.2022 and the Committee did not recommend the proposal at that time. Now the firm presented its proposal for reconsideration. After detailed deliberation, the committee reiterated its earlier recommendation.
7	DTPa-HBV-IPV + Hib vaccine [INFANRIX HEXA] [Post Approval Change] [12-01/GSK pharma/PAC-InfarixHexa/20-BD]	M/s GlaxoSmithKline Pharmaceutical Limited	The firm presented updated package insert of Diphtheria, tetanus, pertussis (acellular component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus type b conjugate vaccine (adsorbed) [INFANRIX HEXA]. After detailed deliberation, the committee recommended for updation of package insert in line with EU SmPC and as presented.
8	Varicella vaccine live IP [Post Approval Change] [12-68/GSKpharma/PAC-Varilrix/16-BD]	M/s GlaxoSmithKline Pharmaceutical Limited	The firm presented updated package insert of Varicella vaccine live. After detailed deliberation, the committee recommended for updation of package insert in line with EU SmPC and as presented.