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 05.02.2024 (through web-conferencing)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 05.02.2024 and recommended the following:

Sr. No.	Name of Vaccine & File no.	Name of Firm	Recommendations
1	Herpes Zoster Liquid Vaccine [Presubmission] [X-11026/129/2019-BD]	M/s GlaxoSmithKline Pharmaceuticals Limited (GSK)	The proposal was deferred as per the request of the firm.
2	Herpes Zoster Vaccine (recombinant, adjuvanted) [Brand name: Shingrix] [PAC] [12-44/GSK/ PAC Shingrix /22-BD]	M/s GlaxoSmithKline Pharmaceuticals Limited (GSK)	Firm presented its proposal for prescribing information (PI) update of Herpes Zoster Vaccine in the approved indication in India in line with USFDA / EMA recommendation and approved SmPc. After detailed deliberation, the committee recommended for updation in the PI subject to submission of supportive data with reference related to clinical study performed.
3	Yellow Fever Vaccine (Live) (I.P) (Re-deliberation) [Phase III clinical trial protocol] [BIO/CT/23/000002]	M/s Serum Institute of India Pvt. Ltd.	In light of SEC (vaccine) recommendation dated 21.02.2023, the firm presented the Phase III clinical trial protocol of Yellow Fever vaccine in ≤ 18 years age group. After detailed deliberation, the committee recommended for approval of the presented protocol with condition that (1) the Phase III clinical trial in children should be initiated only after completion of Phase III clinical trial in adults and submission of clinical trial report to CDSCO for review. 2) More sites should be included to cover all geographical region.

			Dr Savita Verma did not participate in the deliberation.
4	Diphtheria and Tetanus Vaccine (Adsorbed) I.P. [Phase III Protocol] [BIO/CT/23/000154]	M/s. Indian Immunological Limited	The firm presented the Phase III clinical trial protocol of Diphtheria and Tetanus Vaccine (Adsorbed) I.P (Td) in healthy pregnant women. The committee noted that the firm is having permission for the applied vaccine for active immunization against Diphtheria and Tetanus in adult and adolescents. After detailed deliberation, the committee recommended that the firm should submit (1) Developmental & Reproductive Toxicity studies report in animals (2) Post Marketing safety data on the marketed vaccine, (3) Published report on the proposed vaccine
5	Tetanus Vaccine (Adsorbed) I.P. [Phase III Protocol] [BIO/CT/23/000129]	M/s. Indian Immunological Limited	The firm presented the Phase III clinical trial protocol of Tetanus Vaccine (Adsorbed) I.P in healthy pregnant women The committee noted that the firm is having permission for the applied vaccine for active immunization at more than equal to 6 weeks against Tetanus. Also for prevention of tetanus in all age groups following injury or animal bites and to persons who are at increased risk of attaining injuries through their occupation or recreational activities. After detailed deliberation, the committee recommended that the firm should submit (1) Developmental & Reproductive

			Toxicity studies report in animals (2) Post Marketing safety data on the marketed vaccine, (3) Published report on the proposed vaccine
6	Inactivated Tetravalent Influenza vaccine [MA] [12-17/Cadila/16-BD]	M/s. Zydus Lifesciences Ltd	The proposal was deferred as per the request of the firm.
7	RSV Vaccine [Phase III Protocol] [GCT/CT04/FF/2023/40040]	M/s. PPD	The firm presented the Phase III clinical trial protocol no. VAD00004 version 2.0 dated 30 June 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial with the condition that the firm should specify minimum number of subjects from India. Accordingly firm should submit revised protocol for further review by CDSCO.
8	Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Recombinant Vaccine (GARDASIL) [PAC] [12-108/MSD/ PAC-HPV/15-BD]	M/s MSD Pharmaceuticals Ltd.	Firm presented its proposal for update of prescribing information (PI) of the Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Recombinant Vaccine in line with the global PI. The firm informed that the proposed changes are not related to changes in composition and indication approved in Indian population. After detailed deliberation, the committee recommended to update the PI in line with the EMA approval subject to submission of supportive documents with respect to the PI update including inclusion of the source of study in the updated PI.

9	Varicella Vaccine Live I.P [PAC] [12-30/MSD/PAC-Varicella/17-BD]	M/s MSD Pharmaceuticals Ltd.	Firm presented its proposal for update of prescribing information (PI) in line with the global PI. The firm informed that the proposed changes are not related to changes in composition and indication approved in Indian population. After detailed deliberation, the committee recommended to update the PI in line with the USFDA and EMA approval subject to submission of supportive documents with respect to the PI update including inclusion of the source of study in the updated PI.
10	Inactivated Hepatitis A Vaccine adsorbed I.P. (Brand name: Avaxim® 80U) [PAC] [12-93/ Sanofi/PAC-Hepatitis A-PI/ 17-BD]	M/s Sanofi Healthcare India Private Limited	Firm presented its proposal for prescribing information (PI) update of Inactivated Hepatitis A Vaccine adsorbed I.P. After detailed deliberation, the committee recommended that the firm should include the information related to the composition of the vaccine in the updated Prescribing Information in line with permission granted by CDSCO and other information should be included in the PI in line with ANSM, France approved SmPC dated 20 April 2021 based on CCDSv14 dated 16 Mar. 2022 and CCDSv15 dated 24 Sep.2020.