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 06.09.2022 (through web-conferencing)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 06.09.2022 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	Recombinant Hepatitis E Vaccine (Adsorbed) CT [Phase II/III] [BIO/CT/22/000070]	M/s Zydus Lifesciences Limited	Firm presented its proposal for grant of permission to conduct Phase II/III clinical trial of Recombinant Hepatitis E Vaccine (Adsorbed) in subjects aged 16 to 65 years along with the Phase I clinical trial report. Firm also presented pre-clinical studies in mice, rats & rabbits. The committee noted that the Phase II/III trial is proposed with three dose schedule (30mcg/0.5ml/dose) at 0, 1 and 6 months by intramuscular route. (IM) The committee also noted that the similar Hepatitis E vaccine is approved and marketed only in China. After detailed deliberation, the committee recommended that the firm should initially conduct Phase II clinical trial with adequate sample size before proposing for Phase-III clinical trial. Accordingly, firm should submit Phase-II clinical trial protocol before the committee for review.
2	MR vaccine PMS [BIO/CT/22/000078]	M/s Zydus Lifesciences Limited	Firm presented its proposal for grant of permission to conduct active post-marketing surveillance study to evaluate the safety of Measles & Rubella vaccine (Live) I.P. (Freeze Dried) in healthy subjects aged 9-12 months when administered in single dose. The committee noted that the vaccine is approved in age group of 9-12 months when administered as single dose. After detailed deliberation, the

			committee recommended for the conduct of proposed active post-marketing surveillance study.
3	Varicella Vaccine Live Attenuated CT [Phase III] [BIO/CT/22/000084]	M/s Techinvention Lifecare Pvt., Limited	Firm presented its proposal for grant of permission to conduct Phase III clinical trial of Varicella Vaccine Live, attenuated in healthy paediatric subjects aged 1 to 12 years when administered as single dose of 0.5 mL as subcutaneous injection along with the pre-clinical studies data and clinical trial data from clinical trials conducted in China. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-III clinical trial as per the proposed trial protocol.
4	Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), Haemophilus influenzae Type b Conjugate and Poliomyelitis (Inactivated) Vaccine (Adsorbed) (Hexavalent vaccine) Permission for approval of Booster dose indication [BIO/MA/20/000056] (Single dose)	M/s Sanofi Healthcare Limited	Firm presented its proposal for grant of permission of Diphtheria, Tetanus, Pertussis (Whole Cell), Hepatitis B (rDNA), Haemophilus influenza Type b Conjugate and Poliomyelitis (Inactivated) Vaccine (Adsorbed) (Hexavalent vaccine) for administration of booster dose by intramuscular administration in age group of 12-24 months along with the Phase III clinical trial report. After detailed deliberation the committee noted that firm has not conducted the study as per approved clinical trial protocol and the committee recommended that clinical study report is not acceptable as presented.
5	[BIO/MA/20/000055] (Multi dose)		
6	Pneumococcal Polysaccharide Vaccine (23-valent) [Permission to import] [BIO/CT18/FF/2019/17872]	M/s G C Chemie Limited	Firm presented its proposal for grant of permission to import Pneumococcal Polysaccharide Vaccine (23 Valent) proposed for indication of prevention of Pneumococcal infection caused by *Streptococcus Pneumoniae* in adults aged 18 to 65 years when

			administered by intramuscular (IM) injection in single dose of 0.5 ml along with the Phase-III clinical trial report conducted in the country. After detailed deliberation, the committee recommended for grant of permission to import Pneumococcal Polysaccharide Vaccine (23 Valent) proposed for use in adults aged 18 to 65 years when administered in single dose of 0.5 ml.
7	Human Papillomavirus Quadrivalent (Type 6, 11, 16 & 18) Recombinant Vaccine [PAC] 1[2-108/MSD/PAC-HPV/15-BD]	M/s MSD Pharmaceutical Pvt Limited	The proposal was deferred as per the request of the firm.
8	Hexaxim Vaccine suspension for injection in PFS [PAC] [12-16/Sanofi/PAC-Hexaxim/18-BD]	M/s Sanofi Healthcare India Private Limited	Firm presented its proposal for Indian Prescribing Information update for Hexaxim Suspension for injection in Pre-filled Syringe in line with approved EU SmPC. After detailed deliberation, the committee recommended for the proposed updation in line with the EU approved prescribing information/ SmPC.
9	Boostrix Vaccine PAC 12-85/GSK/PAC-Boostrix & Infanrix/16-BD	M/s GlaxoSmithKline Pharmaceuticals Limited	Firm presented its proposal for Indian Prescribing Information update for dTaP Vaccine [Brand Name: Boostrix] based on source NRA (EU) approval. After detailed deliberation, the committee recommended for the proposed updation in line with the EU approved prescribing information/ SmPC.