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 21.11.2022 (through web-conferencing)

The Recommendations:
The SEC (Vaccine) deliberated the proposals on 21.11.2022 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	Recombinant Rabies G Protein Vaccine Type: Phase III CT BIO/CT04/FF/2022/33352	M/s Cadila Pharmaceuticals Limited	The firm presented its proposal for grant of permission to conduct Phase III clinical trial in pediatric population in the age group of 1 year to <18 years. After detailed deliberation, the committee recommended that Phase-III clinical trial protocol should be revised for inclusion of safety as study objectives and accordingly sample size should be increased and should be statistically significant for safety & immunogenicity.
2	Quadrivalent Influenza vaccine Type: MA BIO/MA/22/000088	M/s Cadila Pharmaceutical Limited	The firm presented its proposal for grant of manufacturing permission for Quadrivalent Seasonal Influenza Virus-Like Particle (VLP) Vaccine based on the Phase III clinical trial report. Committee noted the study result. After detailed deliberation the committee recommended for grant of manufacturing permission for Quadrivalent Seasonal Influenza Virus-Like Particle (VLP) Vaccine and further opined that the firm should submit DSMB review report of pediatric study group. The DSMB should comprise of suitable experts including pediatrician/s and the DSMB review report should be submitted to CDSCO for further review.
3	Quadrivalent Influenza vaccine Type: Phase IV CT BIO/CT/22/000085	M/S IQVIA (RDS) Limited	The firm presented its proposal for grant of permission to conduct Phase IV clinical trial of Quadrivalent Influenza vaccine (Split virion) of M/s GlaxoSmithkline Pharmaceuticals Limited. After detailed deliberation, the committee recommended for grant of

			permission to conduct Phase IV clinical trial.
4	20-valent Pneumococcal Conjugate Vaccine (20vPnC) Type: Phase III CT BIO/CT/22/000051	M/s Pfizer Limited	In light of the recommendation of SEC meeting dated 29.08.2022, the firm presented its proposal for grant of permission to conduct Phase III clinical trial of 20-valent Pneumococcal Conjugate Vaccine. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial subject to following conditions: 1. The sample size for determination of OPA titres should be clearly defined in the protocol. 2. The firm should submit independent bio-statistician certificate for sample size calculation.
5	HPV vaccine Type: MA BIO/MA/22/000064	M/s Serum Institute of India Private Limited	The firm presented justification for the inclusion of indication of "Anal cancer & anal intraepithelial neoplasia (AIN) grades 1, 2 and 3" in the prescribing information of Quadrivalent Human Papilloma Virus Vaccine (Recombinant) (qHPV). After detailed deliberation, the committee noted the justification provided by the firm and recommended the inclusion of the indication of "Anal cancer & anal intraepithelial neoplasia (AIN) grades 1, 2 and 3". Also the committee recommended that the firm should carry out post marketing surveillance (PMS) study as per the earlier permission.
6	Recombinant Hepatitis E Vaccine (Adsorbed) Type: Phase II CT	M/s Zydus Lifesciences Limited	In light of the recommendations of SEC meeting dated 06.09.2022, firm presented its proposal for grant of permission to conduct Phase II clinical trial of Recombinant Hepatitis

	BIO/CT/22/000070		E Vaccine (Adsorbed). After detailed deliberation, the committee recommended for grant of permission to conduct Phase II clinical trial as per the presented protocol.
7	Quadrivalent Meningococcal ACWY Conjugate vaccine Type: GCT GCT/CT04/FF/2022/32332	M/s Sanofi Healthcare India Private Limited	The firm presented their proposal for grant of permission to conduct Phase III clinical trial as per protocol No: MEQ00064, Protocol version no 2.0 dated 04 Feb 2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial as per the presented protocol.
8	Inactivated Hepatitis A Vaccine adsorbed I.P. (Brand Name: Avaxim® 80U) Type: PAC 12-93/Sanofi/PAC-Hepatitis A-PI/17-BD	M/s Sanofi Healthcare India Private Limited	The firm presented its proposal for Indian Prescribing Information update for Inactivated Hepatitis A Vaccine adsorbed I.P. (Brand Name: Avaxim® 80U) in line with EU-SmPC-French MA dated 10.07.2019. After detailed deliberation, the committee recommended for the proposed updation in line with the EU-SmPC-French MA dated 10.07.2019.
9	Yellow Fever Vaccine (Live) (Stamaril) single dose / multi dose Vaccine Type: PAC 12-31/Sanofi/PAC-Stamaril/21-BD	M/s Sanofi Healthcare India Private Limited	The firm presented its proposal for Indian Prescribing Information update for Yellow Fever Vaccine (Live) (Stamaril) single dose / multi dose Vaccine in line with EU-SmPC. After detailed deliberation, the committee recommended for the proposed updation in line with the EU-SmPC.