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 25.11.2025 (through hybrid mode)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 25.11.2025 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1	Respiratory Syncytial Virus (RSV) Vaccine (Recombinant, Adjuvanted) New Drug Permission [BIO/IMP/24/000133]	M/s. GlaxoSmithKline Pharmaceuticals Limited	Firm has submitted application for grant of new drug permission of Respiratory Syncytial Virus (RSV) Vaccine (Recombinant, Adjuvanted) along with interim report of Phase III clinical study conducted in India. Firm presented interim report of Phase III clinical study titled "A Phase 3, randomized, placebo-controlled, observer-blind study in India to evaluate immune response, reactogenicity and safety of a single intramuscular dose of RSVPreF3 OA investigational vaccine when administered to older adults ≥60 years of age and adults 50-59 years of age at increased risk of respiratory syncytial virus lower respiratory tract disease" as per the approved protocol along with 1-month safety data. The committee noted the following: - a) Human respiratory syncytial virus (RSV) is a globally prevalent cause of lower respiratory tract infection (LRTI) in all age groups. RSV is increasingly being recognized as an important pathogen in older adults, with infection leading to an increase in hospitalization rates among those aged 65 years and over, and to increased mortality rates among the frail elderly that approach the rates seen with influenza. (Ref: WHO TRS 1024, Annexure 2). b) The Respiratory Syncytial Virus (RSV) Vaccine (Recombinant, Adjuvanted) of the firm is already approved in 68 countries. The vaccine is approved in US, UK, Japan, Australia, Canada & EU for

			the indication for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults 60 years of age and older. c) The vaccine is also approved in USA, EU (30 countries), Canada, Japan, Egypt, Argentina, Trinidad & Tobago, Peru, Kuwait, Qatar and Thailand for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in adults of 50 through 59 years of age who are at increased risk for RSV disease. d) As per the data presented by the firm, approximately 1,34,03,492 doses have been administered across the globe and no additional safety concerns were reported in the post marketing period. e) The firm presented 1-month safety data in Indian population along with interim study report as per the approved protocol. f) The firm is required to submit the stratified data for older adults ≥60 years of age as per the protocol. In view of above and after detailed deliberation, the committee noted the safety and immunogenicity study results of Phase III clinical trial and recommended for grant of new drug permission only after submission of the complete Phase III study report with stratified data for older adults ≥60 years of age and 6-months safety data to CDSCO for further consideration.
2	Inactivated Influenza Vaccine (Split Virion) I.P. (Trivalent) Phase IV clinical trial	M/s. Zydus Lifesciences Ltd.	In light of recommendation of SEC dated 30.04.2024, firm presented Phase IV clinical trial protocol titled “A prospective, single-arm, multicentre, Phase IV clinical trial to evaluate the immunogenicity and safety of Inactivated Influenza Vaccine

	Protocol [BIO/CT/25/000113]		(Split Virion) I.P. (Trivalent) of M/s. Zydus Lifesciences Ltd., in healthy pediatric participants aged 6 months to 17 years. After detailed deliberation, the committee recommended for conduct of the clinical trial with condition that (1) the firm should increase the sample size by 50% in safety arm of the study protocol (2) the clinical trial sites should be geographically distributed across the country and accordingly, the firm should submit revised protocol to CDSCO for further consideration.
3	Hepatitis A (Live) Vaccine, Freeze-dried Phase III clinical trial Protocol [BIO/CT/25/000122]	M/s Sinopharm India Pvt. Ltd.	In light of recommendation of SEC dated 21.12.2022, firm presented Phase III clinical trial protocol titled "A prospective, randomized, double blind, parallel group, active controlled, multicentre, non-inferiority Phase III study to evaluate the immunogenicity and safety of single dose Hepatitis A (Live) vaccine, compared to live attenuated BIOVAC-A in healthy children aged 1-12 years. After detailed deliberation, the committee noted the following: - 1. The proposed formulation has been approved with reduced volume (1 ml to 0.5 ml) and change in excipients by the NRA of country of origin (China) in December, 2023 and January, 2025 with the following conditions: - (a) Stability study should be continued as planned to monitor the change trend of key indicators of this product. If there is any abnormality, it should be reported to the regulatory authority in time.

			(b) The terminal sterilization study should be carried out for in-house diluent as soon as possible. (c) Please continue to strengthen the monitoring and evaluation of adverse events that have not yet been determined to be related to vaccination in pharmacovigilance activities. 2. Period of the post marketing study of the vaccine with new formulation needs to be clarified. 3. The specific reason for the change in volume and excipients of the formulation was not defined clearly. In view of above, the committee recommended that the firm should submit adequate response along with justification and evidences for further deliberation.