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 22.12.2025 (through hybrid mode)

Recommendations:

The SEC (Vaccine) deliberated the proposals on 22.12.2025 and recommended the following:

Sr. No.	Name of Vaccine / Antisera & File no.	Name of Firm	Recommendations
1	Diphtheria, Tetanus and Pertussis (whole cell), Hepatitis-B (r-DNA), Haemophilus Influenzae Type B Conjugate and Inactivated Poliomyelitis Vaccine (Adsorbed) (sIPV from new source) Phase I Clinical Trial Protocol [BIO/CT/24/000080]	M/s Indian Immunological Limited, Hyderabad	In light of recommendation of SEC dated 22.08.2024, firm submitted revised Phase I clinical trial protocol titled, "An open label Single Centric Phase I Clinical Trial to evaluate the safety and immunogenicity of Hexavalent (DTwP-HepB-Hib-IPV) vaccine of HBI when administered in healthy subjects from 16 months to 24 months of age along with the response for the various information / clarification sought by the committee. On review of the response, the committee noted the following: - 1. The firm has developed the Hexavalent vaccine - Diphtheria, Tetanus and Pertussis (whole cell), Hepatitis-B (r-DNA), Haemophilus Influenzae Type B Conjugate and Inactivated Poliomyelitis Vaccine (Adsorbed) using new source of IPV antigens, which are not used in any approved polio vaccines (OPV and IPV) in the country. 2. The Inactivated Polio Vaccine (sIPV) manufactured from the sIPV antigens (new source) have been used only in the country of origin (China) and in two countries Thailand and Pakistan (total 10.01 million doses distributed as per the information furnished). 3. The firm has not submitted Post Marketing Surveillance data for the doses distributed for sIPV. 4. Under the WHO Global Action Plan (GAP III / IV) of Global Polio Eradication Initiatives (GPEI), the National Authority for Containment (NAC) are

			established in countries hosting one or more poliovirus – essential facilities (PEFs) to manage risks from poliovirus in labs after wild polio eradication, ensuring facilities containing live poliovirus samples (like research labs, vaccine makers) meet strict biosafety standards (WHO GAPIII / IV) to prevent accidental release, overseeing national inventories, and certifying compliance for poliovirus-essential facilities through a monitoring system. 5. It is vital that polioviruses stored for research and vaccine manufacturing purposes are safely contained in certified polio-essential facilities (PEFs). 6. The manufacturer of the sIPV has no Poliovirus Containment Certification Scheme (CCS) approval for the manufacturing facility, as presently there is no NAC established in China. 7. South-East Asia Region of WHO including India has been certified polio free by “The Regional Certification Commission (RCC)” on 27th March 2014. 8. Currently, polio is endemic in only 2 remaining countries: Afghanistan and Pakistan. 9. The Global Commission for the Certification of Poliomyelitis Eradication (GCC) declared wild poliovirus type 2 (WPV2) eradicated in 2015 and type 3 (WPV3) eradicated in 2019. Worldwide WPV type 1 (WPV1) cases have dropped considerably and have been limited to a small number of countries. Despite these achievements, the continuing circulation of WPV1 and outbreaks of cVDPV present

			significant obstacles to overcome before total eradication can be reached. 10. The Polio Eradication Strategy 2022-2026: Delivering on a Promise set the goal of a polio-free world by 2026. Achieving this goal requires: (i) permanently interrupting all poliovirus transmission in endemic countries; and (ii) stopping circulating vaccine derived poliovirus (cVDPV) transmission and preventing outbreaks of cVDPV in polio-free regions. 11. Though, sabin strains are less pathogenic than wild and have lower secondary infection rates, but all three Sabin virus types have been linked to vaccine-derived poliovirus (VDPV) outbreaks. Currently, cVDPV2 presents as great a public health threat along with the ongoing circulation of WPV1 in endemic countries. 12. As per Annexure 3 of WHO TRS 993, the Sabin vaccine strains are attenuated, and transmission from vaccine recipients is limited. However, they are unstable on passage in cell culture and the human gut, and can revert to give cVDPVs 13. WHO Global Action Plan for Poliovirus containment (under GPEI) facilities for production and testing of polio vaccine which need to store wild / sabin polio virus need to have strict biorisk management compliance to minimize the risk of facility associated release of poliovirus.

			14. Poliovirus Facility-Associated Risks: - (Ref:https://polioeradication.org/wp-content/uploads/2022/07/WHO-Global-Action-Plan-for-Poliovirus-Containment-GAPIV.pdf) a) Facilities that continue to retain live poliovirus material must assess and control the unique risks associated with the storage and/or handling of poliovirus as the world nears eradication. Ingestion is the natural route of transmission for poliovirus and presents the highest risk for facility personnel as this may occur via contact with contaminated fomites, splash to the oral mucosa or by inhalation of large droplets, some of which will deposit in the pharyngeal region. Immunization with OPV or IPV prevents disease, but immunization neither fully inhibits asymptomatic poliovirus infection nor prevents reinfection of the gut. Estimated infectious doses (ID_{50}) by ingestion, based on studies with infants and children, are $\pm 10^1$ $CCID_{50}$ for wild polioviruses and $\pm 10^3$ $CCID_{50}$ for Sabin strains. b) Immunized adult personnel are likely more resistant than immunologically naïve children, but resistance is dose related and may be overcome by larger ingested doses. Droplets created by sprays, spills and the splash of poliovirus cell cultures (up to 10^8 $CCID_{50}$) and concentrates (10^{11} $CCID_{50}$) constitute one of the highest personnel exposure risks. c) While biosafety measures continue to evolve and improve, workplace acquired infections

			still occur. Several literature reviews and surveys of workplace acquired infections and exposures (laboratory, clinical and vaccine manufacturing settings) found the most commonly identified routes of exposure to infectious agents in the facility environment are parenteral inoculation, spills and splashes to the skin or mucous membranes, ingestion, and animal bites or scratches. These incidents comprise approximately 20% of clearly attributable causes of exposure. In the context of poliovirus exposure, any splashes and spills that may lead to accidental ingestion, including contamination of the hands, may become a route for worker infection. d) In the poliovirus facility, poliovirus content of common materials ranges from a mean of $10^{3.7}$ $CCID_{50}$/g (Sabin) to $10^{4.3}$ $CCID_{50}$/g (wild) in stool samples, to 10^{8} $CCID_{50}$/ml in cell culture harvests, and 10^{11} $CCID_{50}$/ml in concentrates in vaccine production facilities. e) Peer-reviewed research has examined facility-associated release of poliovirus and poliovirus workplace acquired infection and incidents and underscores the need for heightened biosafety and biosecurity practices, comprehensive risk assessment and control strategies, appropriate facility design and operations and emergency plans. Individuals and facility workers fully vaccinated against poliovirus are still capable of becoming

			infected and shedding live virus, presenting a risk of asymptomatic community spread following a laboratory acquired infection. This is of particular concern because most laboratory acquired infections are not able to be attributed to specific incidents identified in the lab, and thus infections may occur without the workers realizing they have been exposed. In addition to exposure from workers infected due to their work with poliovirus, community members may be exposed to infectious agents from the facility through various means like workers' contaminated skin or clothing; the release of contaminated air; contaminated effluents and wastewater recovered from secondary sewage treatment plants; the uncontrolled transport of infectious material; solid waste transported to landfills; contaminated equipment or materials removed from the facility; the escape of infected animals. f) Therefore, it is required by all countries to minimise the risk of new outbreaks of poliomyelitis (polio), which includes minimizing the risk of polioviruses being released into the environment or communities from laboratories, vaccine production facilities, or other facilities that handle or store polioviruses. g) It is important to prevent reintroduction of the polio viruses into the community due to wild type polio viruses and cVDPVs once poliomyelitis is eradicated.

			15. There is no study data for Hexavalent Vaccine containing sIPV sourced from M/s. Sinovac, China in any population. 16. The product sIPV is also registered in three countries i.e., Belarus, Peru and Argentina but there is no distribution till date. In view of above and after detailed deliberation, the committee recommended that considered decision cannot be taken at this stage for conduct of Phase I clinical trial of Hexavalent vaccine - Diphtheria, Tetanus and Pertussis (whole cell), Hepatitis-B (r-DNA), Haemophilus Influenzae Type B Conjugate and Inactivated Poliomyelitis Vaccine (Adsorbed) containing sIPV from new source of IPV antigens.
2.	Diphtheria-Tetanus-whole cell Pertussis-Hepatitis B-Haemophilus influenzae type b and inactivated Poliovirus (DTwP-rHepB-Hib-IPV) vaccine, (Adsorbed). New Drug Permission [BIO/MA/25/000159]	M/s Biological. E Limited	Firm presented Phase III clinical study report titled: A prospective, single blind, randomised, active controlled, Phase III study to assess the immunogenicity and safety of Biological E's Liquid Hexavalent Vaccine (DTwP-rHepB-Hib-IPV) in 6-8 weeks old healthy infants in a 6-10-14 weeks dosing schedule. The committee noted the following: - 1. The firm presented the results of safety and immunogenicity of the vaccine in the study population. 2. The firm also presented the non-interference of immune response of the study vaccine with co-administered EPI vaccines in one subgroup. 3. Firm will monitor the safety of the clinical trial participants till 236 days and shall submit the integrated CSR with additional safety follow up data as per approved protocol to CDSCO once completed. 4. The demographic data of the participants with respect to length and corresponding weight were

			found to be inadequate and the same should be submitted for further review. 5. The DSMB recommendations was not conclusive with respect to SAEs reported and needs to be reviewed by a committee of experts constituted under the chairmanship of experienced Senior pediatrician. In view of above and after detailed deliberation, the committee noted the safety and immunogenicity study results of Phase III clinical trial as presented by the firm and recommended that the firm should submit the response with respect to demographic data and DSMB recommendations for further deliberation. (Dr. Savita Verma did not participate in the deliberation)
3.	Typhoid Conjugate Vaccine (Bivalent) Phase II Interim Analysis Report of Phase II / III protocol [BIO/CT/24/000153]	M/s Serum Institute of India Pvt. Ltd.	Firm presented clinical study report of Phase II part of Phase II/III clinical trial titled "A Phase II/III, Double-Blind, Randomized, active-controlled, multicentric study to evaluate the safety, Immunogenicity and lot-to-lot consistency of a bivalent conjugate vaccine against *Salmonella enterica serovars Typhi* and Paratyphi A in healthy individuals aged 6 months to 65 years. The committee noted the interim Phase II clinical study report with following observations: - 1. The firm presented only the safety and tolerability results of the Typhoid Conjugate Vaccine (Bivalent) conducted in healthy individuals aged ≥18 to ≤65 years. 2. The firm did not present any immunogenicity data of the study participants. 3. The immunogenicity testing of the samples of Phase II and Phase III

			will be performed together at the central laboratory as per approved protocol. 4. The firm will also determine the immune persistence of test and reference vaccine. After detailed deliberation, the committee recommended for the conduct of Phase III trial as per approved protocol and also recommended that the firm should establish the efficacy of the study vaccine in terms of the severity of the disease, hospitalization etc. (Dr. Savita Verma did not participate in the deliberation)
4.	Typhoid Conjugate Vaccine (Bivalent) Phase III Clinical Trial protocol [9 to 12 Months and 15 to 24 Months] [BIO/CT/25/000167]	M/s Serum Institute of India Pvt. Ltd.	Firm presented Phase III clinical trial protocol titled, A Phase 3 double-blind, randomized, active-controlled multicentric study to evaluate the safety, immunogenicity and Immune non-interference of a bivalent conjugate vaccine against Salmonella enterica serovars Typhi and Paratyphi A in healthy children aged 9 to 12 and 15 to 24 months. The committee noted the following: - 1. The study is titled as evaluation of immune non-interference with concomitant vaccines, however, the effect of concomitant medication is mentioned under secondary objective instead of primary objective. 2. Further, it is also observed that only small subset of participants (218 in the test group and 109 in the reference group out of 1308 participants) is proposed for immune non-interference with concomitant vaccines. 3. The firm should revise the protocol to clearly specify that the concomitant vaccines will be MMR and Pneumosil or MMR and Hexasiil. 4. As per WHO Preferred Product

			Characteristics (PPC) for Bivalent Salmonella Typhi, it is required that O:2 LPS to be used as the target polysaccharide antigen for S. paratyphi A. After detailed deliberation, the committee recommended that the firm should submit revised protocol with increased sample size and amendment as per the above observations to CDSCO for further consideration..
5.	Human Papillomavirus 9-Valent Vaccine, Recombinant [Serotypes: Types 6 L1, 11 L1, 16 L1, 18 L1, 31 L1, 33 L1, 45 L1, 52 L1 & 58 L1] Phase IV Clinical Trial Protocol [BIO/CT/25/000166]	M/s MSD Pharma Ltd.,	In light of recommendation of SEC dated 26.03.2025 and as per conditions of permission dated 05.08.2025, firm presented Phase IV clinical trial protocol titled " A Phase IV Open-Label Study to Evaluate the Safety and Immunogenicity of 9vHPV Vaccine Administered as 2-Dose Regimen in 9- to 15-Year-Old Boys and Girls in India". After detailed deliberation, the committee recommended for conduct of the clinical trial with condition that (1) the number of evaluable participants should be 200, equally distributed as 100 boys and 100 girls (2) the firm should present the safety and immunogenicity data together and separately for boys and girls participants (3) the clinical trial sites should be geographically distributed across the country and accordingly, the firm should submit revised protocol to CDSCO for further consideration.