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 11.10.2022 (through web-conferencing)

The Recommendations:
The SEC (Vaccine) deliberated the proposals on 11.10.2022 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-Valent) CT [Phase IV] [BIO/CT/22/000063]	M/s Serum Institute of India Pvt., Limited	Firm presented its proposal for grant of permission to conduct Phase IV clinical trial of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-Valent) to evaluate the Pneumococcal Nasopharyngeal carriage in the age group of 15 to 21 Months. The committee noted that, earlier this committee has recommended the vaccine for additional indication for administration in 2+1 dose schedule (6 weeks, 14 weeks & 9 months) After detailed deliberation, the committee recommended for grant of permission to conduct Phase IV clinical trial of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-Valent) subject to the approval of vaccine for administration in 2+1 dose schedule (6 weeks, 14 weeks & 9 months) by CDSCO. Further, the firm is required to vaccinate the unvaccinated subject participants with the approved Pneumococcal vaccine after collection of swab sample.
2A	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-Valent) [Compliance of Manufacturing Permission condition] [BIO/MA/20/000001]	M/s Serum Institute of India Pvt., Limited	Firm presented its request for grant of waiver for the condition of conduct of Post Market Surveillance (PMS) in the manufacturing permission of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-Valent) with 3+0 dose schedule. Firm provided the justification that, the firm has conducted three Phase III clinical trials overseas for evaluation of persistence of IgG titres. The committee noted that the Phase III clinical trial conducted in India was

			a descriptive and bridging clinical study. Hence, after detailed deliberation, the committee recommended that firm should conduct the Post Market Surveillance (PMS) study to monitor persistence of IgG titres in compliance with the condition of Marketing permission granted earlier in reasonable number of subjects.
2B	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-Valent) [Additional Indications] [BIO/MA/20/000001]	M/s Serum Institute of India Pvt., Limited	Firm presented its proposal for grant of permission for additional indications of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (10-Valent) [3+0 dose schedule] as below: 1. 3+1 vaccination schedule (6, 10, 14 weeks primary vaccination and booster at 9 months or 12 to 15 months) 2. Two dose catch up vaccination schedule [in 2nd year of life] for unvaccinated children. 3. Active immunization against Acute otitis media Firm presented overseas clinical trial data for these indications. After detailed deliberation, the committee recommended that firm should submit relevant clinical trial data in statistically significant Indian population for consideration of above additional indications.
3	Tetanus toxoid, reduced diphtheria toxoid, recombinant pertussis vaccine CT [Phase III] BIO/CT/22/000045	M/s Abbott India Limited	The proposal was deferred as per the request of the firm.
4	Human Papillomavirus Quadrivalent (Type 6, 11, 16 & 18) Recombinant Vaccine [Post Approval Change] [12-108/MSD/PAC-HPV/15-BD]	M/s MSD Pharmaceutical Pvt., Limited	The firm presented updated PI. After detailed deliberation the committee recommended that the firm should retain the no. of subject in the updated package insert as in the original and reorganize the

			presentation of the Indian study as discussed during the meeting. Accordingly, the firm should submit the revised package insert to CDSCO.