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 23.03.2023 (through web-conferencing)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 23.03.2023 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	Typhoid Vi Conjugate Vaccine with Yellow Fever Vaccine [Phase IV CT] [BIO/CT/23/000011]	M/s Zydus Lifesciences Limited.	Firm presented its proposal for conduct of Phase IV clinical trial of Typhoid Vi Conjugate Vaccine I.P. (TCV) with Yellow Fever Vaccine (YFV). After detailed deliberation, the committee recommended that the firm should revise the Phase IV clinical trial protocol as below: 1. Blood sample should not be withdrawn at visit 2. 2. There should be two reference groups. One group should be administered with Yellow fever vaccine and other group should be administered with Typhoid conjugate vaccine. 3. The sample size, primary and secondary endpoints should be defined in accordance with the groups. Accordingly, the firm should submit revised clinical trial protocol for further deliberation.
2	Inactivated Influenza Vaccine (Split Virion) IP (Tetravalent) [MA [Additional Indication]] [BIO/MA/22/000146]	M/s Zydus Lifesciences Limited	Firm presented its proposal for grant of permission for additional indication along with Phase-III clinical trial report of Inactivated Influenza Vaccine (Split Virion) IP (Tetravalent). After detailed deliberation, the committee considered the results of the Phase III clinical trial and recommended for grant of permission for additional indication of Inactivated Influenza Vaccine (Split Virion) IP (Tetravalent) (0.5 ml) with 2 dose

			schedule in healthy children aged 6 to 35 months.
3	Dengue Tetravalent Vaccine (Live, Attenuated) [Phase I/II CT] [BIO/CT/23/000007]	M/s Serum Institute of India Pvt. Limited	Firm presented its proposal for conduct of Phase I/II clinical trial of Dengue Tetravalent Vaccine (Live, Attenuated) After detailed deliberation, the committee recommended that the firm should revise the Phase I/II clinical trial protocol as below: 1. The trial design should be seamless with Phase I followed by Phase II along with DSMB review after Phase-I. The clinical trial report of Phase-I with DSMB recommendations should be submitted before initiation of Phase-II. 2. The clinical trial should be stratified and conducted in adult subjects initially and then in pediatric subjects. 3. The inclusion of seropositive and seronegative subjects should be clearly defined in the protocol. Accordingly, the firm should submit revised clinical trial protocol for further deliberation.
4	Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14- Valent) I.P. [Phase III CT [Booster dose]] [BIO/CT/23/000006]	M/s Biological E Limited	Firm presented its proposal for conduct of Phase III clinical trial of booster dose of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (14- Valent) I.P. After detailed deliberation, the committee recommended that the firm should revise the Phase III clinical trial protocol as below: 1. Minimum sample size should be defined which should be statistically significant.

			2. OPA analysis and RCD plots should be defined as end points in the protocol. Accordingly, the firm should submit revised clinical trial protocol for further deliberation. *Dr Savita Verma did not participate in the deliberation.