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 31.10.2023(through web-conferencing)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 31.10.2023 and recommended the following:

Sr. No.	Name of Vaccine & File no.	Name of Firm	Recommendations
1	Mycobacterium Tuberculosis (Live Attenuated) Vaccine [Phase 1/2 clinical trial protocol] [BIO/CT/23/000032] (Redeliberation)	M/s. Bharat Biotech International Limited, Hyderabad	The proposal of firm was deliberated in the SEC dated 16.05.3023 and was deferred on 18.07.2023 as per firm's request. Based on the recommendations of the SEC, the firm presented the revised Phase I/II clinical trial protocol of Mycobacterium Tuberculosis (Live Attenuated) Vaccine. After detailed deliberation, the committee recommended as below: 1) The firm should separate the protocol for Phase I and Phase II clinical trial and resubmit revised Phase I protocol with safety as primary endpoint in 30 QFT negative healthy subjects and criteria of QFT negative should be included in inclusion criteria. The firm should submit the revised Phase I protocol to CDSCO for further consideration. After completion of the Phase I study, the firm should submit the Phase I results after DSMB review for further deliberation. 2) Further, the firm should revise the Phase II protocol as follows: a) Number of subjects in QFT negative and QFT Positive should be recalculated for statistical outcome. b) Primary end point of phase II study should be

			immunogenicity and secondary end point should be safety. c) Firm should furnish the list of laboratories with specific tests to be carried out. Accordingly, the firm should revise the protocol for phase II clinical trial for further deliberation. (Dr. Savita Verma did not participate in deliberation).
2	Typhoid (Vi Capsular Polysaccharide) Tetanus Toxoid Conjugate Vaccine [Phase IV clinical trial protocol] [BIO/CT/23/000112]	M/s. Bharat Biotech International Limited, Hyderabad	The firm presented the Phase IV clinical trial protocol of Typhoid (Vi Capsular Polysaccharide) Tetanus Toxoid Conjugate Vaccine. After detailed deliberation, the committee recommended to revise the protocol as below; 1) Title of the clinical trial to be changed as Phase-III. 2) (a) Past history of typhoid disease in last 5 years (b) History of immunization with Typhoid vaccine in last 5 years should be included in the exclusion criteria. Accordingly, the firm should submit revised protocol to CDSCO for further consideration.
3	13 Valent Pneumococcal Conjugate Vaccine [Phase III clinical trial protocol] [BIO/CT/23/000101]	M/s. Novo Medi Lifesciences Ltd.	The firm presented the Phase III clinical trial protocol of 13 Valent Pneumococcal Conjugate Vaccine. After detailed deliberation, the committee recommended to increase the sample size for Cohort

			II (age group 6 years to 50 years) to a statistically powered sample size. Accordingly, the firm should submit revised protocol for further deliberation.
4	20-Valent Pneumococcal Conjugate Vaccine (20vPnC) [Phase III (Re-deliberation)] [CT/22/000015]	M/s. Pfizer Ltd.	In light of earlier recommendation, the firm presented the Phase III clinical trial protocol no. B7471024 of 20 valent pneumococcal conjugate vaccine (20vPnC). After detailed deliberation, the committee recommended for the grant of permission to conduct the clinical trial as per revised protocol
5	Unadjuvanted RSV Maternal Vaccine [Phase III Protocol Amendment] [CT/120/20-DCG(I)]	M/s. GSK Pharmaceuticals Ltd.	The firm presented protocol amendment 5 dated 23 Feb 2023 Protocol no. 212171(RSV-MAT-009). After detailed deliberation the committee recommended for the protocol amendment as presented by the firm.
6	Meningococcal Conjugate Vaccine [Phase III Protocol Amendment] [CT/159/21/DCG(I)]	M/s. Sanofi Healthcare (I) Pvt. Ltd.	The proposal was deferred as per the request of the firm.