Minutes of the Meeting of Subject Expert Committee (SEC) - Vaccine to review proposals and advice Drugs Controller General (India) in matters for Biologicals held on 16.05.2023 (through web-conferencing)

The Recommendations:
The SEC (Vaccine) deliberated the proposals on 16.05.2023 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	Mycobacterium Tuberculosis (Live Attenuated) Vaccine [Phase I/II CT] [BIO/CT/23/000032]	M/s. Bharat Biotech International Ltd., Hyderabad.	Firm presented the proposal for grant of permission to conduct Phase–I/II clinical trial for MTBVAC vaccine (freeze-dried powder containing live attenuated Mycobacterium tuberculosis (M. tb). After detailed deliberation, the committee recommended that the firm should initially conduct Phase I clinical trial as a safety study on the test vaccine without comparator followed by Phase II clinical trial as a comparator study after DSMB recommendation. Further, the firm should clarify the following in the revised protocol: 1. Rationale/justification for planning of safety data review by DSMB after 7 days of administration of dose. 2. Treatment plan for any subject, who may develop TB disease in the 1year follow-up period and their analysis plan. 3. Whether house hold contacts, recovered patients, and subjects with previous history of TB will be included or not. 4. List of Principal investigators along with details of clinical trial sites Accordingly, firm should submit revised Phase I/II clinical trial protocol for further deliberation

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2	Quadrivalent Human Papilloma Virus (Serotypes 6,11,16 &18) Vaccine (Recombinant) (CERVAVAC® Vaccine) [Phase IV CT] [BIO/CT/23/000031]	M/s Serum Institute of India Pvt. Ltd., Pune	Firm presented the proposal for grant of permission to conduct Phase IV clinical trial of single dose Quadrivalent Human Papilloma Virus (Serotypes 6,11,16 &18) Vaccine (Recombinant) in girls/woman of age group 9 to 14 years and 15 to 20 years. After detailed deliberation, the committee recommended that the trial design should be Phase III clinical trial with following changes: 1) The design should have efficacy endpoint. 2) 01, 06,12 months blinded analysis may be used to decide on continuation of trial, based on any infection findings etc. in addition to DSMB review. Further trial stoppage criteria should also be described in the protocol. 3) 18 months interim un-blinded immunogenicity/efficacy analysis should be included in the protocol. 4) As proposed by the firm, urine samples will be collected from all enrolled participants and additionally cervical swab will be collected from all consented participants of 18 years and above at the baseline & every 6months upto 5 years. Accordingly, firm should submit revised Phase III clinical trial protocol for further deliberation. *Dr. Savita Verma did not participate in the deliberation.

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3	Dengue Tetravalent Vaccine (live, attenuated) (DEN-302) [Phase III clinical trial (Re-deliberation)] [BIO/CT/22/000121]	M/s IQVIA Pvt. Ltd.,	In light of the recommendation of SEC (vaccine) meeting dated 24.01.2023, the firm presented its proposal for grant of permission to conduct Phase III clinical trial of Dengue Tetravalent Vaccine (live, attenuated) (DEN-302) containing DEN1: ≥ 3.3 log10 PFU/dose, DEN2: ≥ 2.7 log10 PFU/dose, DEN3: ≥ 4.0 log10 PFU/dose, DEN4: ≥ 4.5 log10 PFU/dose of 0.5 mL along with additional data &justification of proposed Phase III clinical trial protocol wherein they are proposing safety and immunogenicity study. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial of Dengue Tetravalent Vaccine (live, attenuated) (DEN-302) after submission of revised Phase III clinical trial protocol removing blood withdrawal at visit 3 (Day 30). Accordingly, the firm should submit revised Phase III clinical trial protocol to CDSCO.
4	Live Attenuated Varicella Vaccine IP [Phase III CT] [BIO/CT/23/000048]	M/s Novo Medi Sciences Private limited, Khargar Panvel	Firm presented its proposal for grant of permission to conduct Phase III clinical trial of Live Attenuated Varicella Vaccine IP with change in formulation as compared to approved formulation of Live Attenuated Varicella Vaccine IP. After detailed deliberation, the committee recommended for grant of permission for conduct of Phase III clinical trial of the vaccine as per protocol presented.

5	Varicella-Zoster Virus (VZV) vaccine [Phase I CT] [BIO/CT/23/000027]	M/s Cadila Pharmaceuticals Limited, Ahmedabad	Firm presented its proposal for grant of permission for conduct of Phase I Clinical Trial of Varicella-Zoster virus (VZV) vaccine along with pre-clinical data. After detailed deliberation, the committee recommended that firm should submit single dose toxicity data as per the provisions of NDCT Rules, 2019. Further, firm should revise the Phase I clinical trial protocol as follows: 1. Comparator arm should be removed from the trial design. 2. Volume of blood to be withdrawn for analysis should be reduced. Accordingly, the firm should submit revised Phase I clinical trial protocol for further deliberation.
6	Typhoid Vi Conjugate vaccine I.P. [Active Post marketing surveillance study (PMS) Report] [BIO/CT/21/000130]	M/s Zydus Lifesciences Limited, Ahmadabad	Firm presented active post marketing surveillance study (PMS) report of Typhoid Vi Conjugate vaccine IP conducted in children, infants, adults of 3000 subjects from 6 months to 45 years of age. After detailed deliberation, the committee noted the results of the Post marketing surveillance study (PMS) Report.

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7	VAC52416 (JNJ-78901563 [ExPEC9V]) (Phase III CT) [GCT/CT04/FF/2023/36174]	M/s ICON Pharmaceuticals Research Associate India, Andheri, East Mumbai	Firm presented its proposal for grant of permission for conduct of Phase III clinical trial of VAC52416 (JNJ-78901563 [ExPEC9V]) vaccine along with Phase I & II clinical trial data and also stated that Phase-III clinical trial is already ongoing in other countries. After detailed deliberation, the committee recommended for grant of permission for conduct of Phase III clinical trial of the vaccine as per presented protocol.