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 18.07.2023(through web-conferencing)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 18.07.2023 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	Typhoid Vi-Conjugate vaccine with MR vaccine [Phase-IV clinical trial report] [BIO/CT/20/000044]	M/s Zydus Lifescienes Ltd., Ahmedabad	Firm presented the Phase-IV clinical trial report for Typhoid Vi-Conjugate vaccine with MR Vaccine. After detailed deliberation, the committee noted the results with following observations: 1) There are many major protocol deviations. 2) In various groups, the evaluable subjects for immunogenicity were lesser than that defined in the protocol
2	Typhoid Vi-Conjugate vaccine with Yellow Fever Vaccine [Phase-IV clinical trial (re-deliberation)] [BIO/CT/23/000011]	M/s Zydus Lifesciences Ltd., Ahmedabad	In light of the recommendation of SEC (vaccine) meeting dated 23.03.2023, the firm presented the revised Phase IV clinical trial protocol for grant of permission to conduct Phase IV clinical trial of Typhoid Vi Conjugate vaccine with Yellow Fever Vaccine. After detailed deliberation, the committee recommended the protocol with minimum number of 40 subjects with age stratification as below: 1) 9 months to 5 years 2) ≥ 5 years to 12 years 3) ≥12 years to 18 years 4) ≥18 years and above Firm should also include more government sites. Accordingly, firm should submit the revised protocol to CDSCO.
3	Hepatitis A vaccine (MA- Additional indication) [BIO/IMP/23/000051]	M/s Prosper Channel Limited, Gurgaon	Firm presented its proposal for grant of permission to manufacture Hepatitis A vaccine for additional

			indication for active immunization against infection caused by Hepatitis A virus for children of 1-15 yrs. The committee noted that earlier, CDSCO has granted import permission for Hepatitis A Vaccine for adult population (Age 18-60 years). Also, the same vaccine from same manufacturer is already approved for active immunization against Hepatitis A virus in 1 to 15 years of age group in the country. In view of above, after detailed deliberation, the committee recommended for grant of permission for additional indication for active immunization against Hepatitis A virus in 1 to 15 years of age group with the condition to conduct PMS study in 500 subjects.
4	Mycobacterium Tuberculosis (Live Attenuated) Vaccine [Phase I/II clinical trial (re-deliberation)] [BIO/CT/23/000032]	M/s Bharat Biotech Limited, Hyderabad	The proposal was deferred as per the request of the firm.
5	Dengue Tetravalent Vaccine (Live, Attenuated) [Phase I/II clinical trial (re-deliberation)] [BIO/CT/23/000007]	M/s Serum Institute of India Pvt. Ltd. Pune	In light of the recommendation of SEC (vaccine) meeting dated 23.03.2023, the firm presented the revised protocol for grant of permission to conduct Phase I/II clinical trial of Dengue Tetravalent Vaccine (Live, Attenuated) After detailed deliberation, the committee recommended for grant of permission to conduct Phase I/II clinical trial of Dengue Tetravalent Vaccine (Live, Attenuated) as per the presented protocol.

6	Yellow Fever Vaccine (Live) (I.P) [Phase II/III clinical trial (re-deliberation)] [BIO/CT/22/000153]	M/s Serum Institute of India Pvt. Ltd. Pune	In light of the recommendation of SEC (vaccine) meeting dated 21.02.2023, the firm presented the revised protocol for grant of permission to conduct Phase II/III clinical trial of Yellow Fever Vaccine (Live) (I.P). After detailed deliberation, the committee recommended to submit revised protocol with primary objective of assessment of immunogenicity in Phase-II. Further, sample size for Phase-III should be re-calculated. Accordingly, firm should submit revised protocol for further deliberation.
7	Varicella-Zoster Virus (VZV) vaccine [Phase I clinical trial (re-deliberation)] [BIO/CT/23/000027]	M/s Cadila Pharmaceuticals Limited, Ahmedabad	The proposal was deferred as per the request of the firm.
8	Oral Cholera Vaccine [MA] [BIO/MA/23/000032]	M/s Bharat Biotech International Ltd	Firm presented the proposal for grant of permission to manufacture Cholera Vaccine (Inactivated, Oral) for sale or for distribution along with interim report of Phase III clinical trial. After detailed deliberation, the committee recommended to submit complete Phase III clinical trial report up to 180 days as per approved protocol for further deliberation. Also the committee recommended for inspection of the clinical trial sites. *[Dr Savita Verma didn't participate in the deliberation]