

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 21.12.2022 (through web-conferencing)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 21.12.2022 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human) Type: Phase III CT BIO/CT04/FF/2022/33589	M/s Biological E Limited, Hyderabad	In light of the recommendations of SEC meeting dated 26.04.2022, firm presented its proposal for grant of permission to conduct Phase III clinical trial of Japanese Encephalitis Vaccine Inactivated (Adsorbed, Human). After detailed deliberation, the committee recommended for conduct of Phase III clinical trial with condition to vaccinate the subjects of 9-12 months age groups with Pneumococcal polysaccharide conjugate (PCV) vaccine and Inactivated Poliomyelitis Vaccine (IPV) also at the same time. Accordingly, the firm should submit revised clinical trial protocol to CDSCO.
2	Inactivated Poliomyelitis Vaccine (Adsorbed) (reduced dose) Type: Phase II CT BIO/CT/22/000101	M/s Biological E Limited, Hyderabad	Firm presented its proposal for grant of permission to conduct Phase II clinical trial of Inactivated Poliomyelitis Vaccine (Adsorbed) [reduced dose]. After detailed deliberation, the committee recommended for conduct of Phase II clinical trial with condition that the firm should administer additional dose of IPV (reduced dose) to the participants, if they have not achieved adequate seroprotection. Accordingly, the firm should submit revised clinical trial protocol to CDSCO.

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3	Hexavalent Vaccine (DTwP-rHepB-IPV-Hib) Type: Phase I/II CT BIO/CT/22/000107	M/s Biological E Limited, Hyderabad	Firm presented its proposal for grant of permission to conduct Phase I / II Clinical trial of Hexavalent Vaccine (DTwP-rHepB-IPV-Hib). After detailed deliberation, the committee recommended that firm should conduct Phase I clinical trial before Phase II with revised sample size. Accordingly, the firm should submit revised Phase I clinical trial protocol with revised sample size for further deliberation by the committee.
4	Cholera Vaccine (Inactivated <i>Vibrio cholerae</i> , MS 1568, Oral) Type: Phase III CT (amendment protocol) BIO/CT/22/000103	M/s Bharat Biotech International Limited, Hyderabad	Firm presented its proposal for inclusion of additional safety arm of 1800 subjects as an addendum to the already approved Phase III clinical trial protocol of Cholera Vaccine (Inactivated <i>Vibrio cholerae</i> , MS 1568, Oral). After detailed deliberation, the committee recommended to conduct the trial with additional safety arm of 1800 subjects as an addendum to the already approved Phase III clinical trial protocol of Cholera Vaccine (Inactivated <i>Vibrio cholerae</i> , MS 1568, Oral). NB: Dr Savita Verma did not participate in the deliberation.
5	Pneumococcal Polysaccharide Conjugate vaccine, IP (15-Valent) Type: MA BIO/CT21/BO/2022/33887	M/s Tergene Biotech Limited, Hyderabad	Firm presented its proposal for grant of permission to manufacture for sale and distribution of Pneumococcal Polysaccharide Conjugate Vaccine, IP (15-Valent) with three dose schedule (6, 10 & 14 weeks) [3 +0] along with the report of Phase III clinical trial conducted in the country. The committee noted the results of Phase III clinical trial.

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			After detailed deliberation, the committee recommended for grant of permission to manufacture & market Pneumococcal Polysaccharide Conjugate Vaccine, IP (15-Valent) with three dose schedule [3 +0] for the age group of 6, 10 & 14 weeks.
6	Oral Cholera Vaccine Type: MA BIO/IMP/19/000049	M/s TechInvention Lifecare Pvt. Ltd., Mumbai	Firm presented its proposal for grant of permission to import for sale and distribution of Oral Cholera Vaccine along with Phase III clinical trial report. The committee noted the results of Phase III Clinical trial. After detailed deliberation, the committee recommended for grant of permission to import & market Oral Cholera Vaccine.
7	Hepatitis A (Live) Vaccine, (Freeze-dried) Type: MA BIO/IMP/22/000083	M/s Sino pharma Limited	Firm presented its proposal for grant of permission to import for sale and distribution of Hepatitis A vaccine (Freeze Dried) with 0.5ml diluent (new formulation) without local clinical trial. After detailed deliberation, the committee recommended that firm should conduct Phase III clinical trial of Hepatitis A vaccine (Freeze Dried) with 0.5ml diluents with the proposed changes in formulation.