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 04.02.2021 (through web-conferencing)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 04.02.2021 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	BIO/MA/20/000055 Hexavalent Vaccine (MA)	M/s Sanofi Healthcare India Private Limited	Firm presented its proposal for grant of permission to manufacture Hexavalent Vaccine along with safety, immunogenicity and lot to lot consistency data from Phase III clinical trial in the country. After detailed deliberation the committee recommended for grant of permission to manufacture and market hexavalent vaccine subject to the condition that firm should continue the ongoing study on booster dose and submit safety & efficacy data as and when available. Further, the committee recommended that the clinical trial sites may be got audited for compliance with GCP requirements.
2	BIO/MA/20/000056 Hexavalent Vaccine (MA)	M/s Sanofi Healthcare India Private Limited	
3	BIO/MA/20/000065 Quadrivalent Inactivated Influenza Vaccine (CT)	M/s Cadila Pharmaceuticals Limited, Ahmedabad	Firm presented its proposal for grant of permission to conduct Phase III clinical trial in the country. After detailed deliberation the committee recommended that the clinical trial protocol should be revised with respect to the following: 1. The study should be double blind with an active comparator arm. 2. The sample size should be revised accordingly with adequate representation from all the target age groups. 3. The study should be carried out in step down design starting with adult age group and proceed to other age groups in graduated manner. Accordingly, firm should submit separate clinical trial protocol before the committee for further review.

4	BIO/IMP/20/000072 Pneumococcal vaccine Prevnar-13 MA (additional indication)	M/s Pfizer Limited, Mumbai	Firm presented its proposal for grant of permission to import and market Pneumococcal vaccine (Prevnar-13) for the age group between 18 to 49 years. After detailed deliberation, the committee recommended that the firm should submit safety and immunogenicity data in Indian population for the proposed age group.
5	BIO/CT/20/000138 Inactivated Japanese Encephalitis Vaccine (Phase IV CT)	M/s Bharat Biotech International Limited, Hyderabad	Firm presented its proposal for grant of permission to conduct Phase IV clinical trial in age ≥6 to < 8 months to demonstrate non-interference of Measles, Mumps & Rubella vaccine. After detailed deliberation, the committee recommended that the firm should initially generate safety and immunogenicity data in the proposed age group before carrying out non-interference study with MMR vaccine. Accordingly the firm should submit revised clinical trial protocol for further review.
6	BIO/CT/20/000139 Quadrivalent Influenza Vaccine (CT Phase III)	M/s Bharat Serums And Vaccines Limited , Mumbai	Firm presented its proposal for grant of permission to conduct Phase III clinical trial of Quadrivalent Influenza Vaccine along with clinical trial protocol. After detailed deliberation the committee recommended that the clinical trial protocol should be revised with respect to the following: 1. The study should be double blind with an active comparator arm. 2. The sample size should be revised accordingly with adequate representation from all the target age groups. 3. The study should be carried

			out in step down design starting with adult age group and proceed to other age groups in graduated manner. 4. The inclusion & exclusion criteria should be well defined and justified. Accordingly, firm should submit separate clinical trial protocol before the committee for further review.
7	BIO/CT/20/0001187 Pneumococcal conjugate (15 valent) vaccine (CT Phase III)	M/s Teregene Biotech Pvt. Ltd. Hyderabad	Firm presented its proposal for grant of permission to conduct Phase III clinical trial of Pneumococcal conjugate (15 valent) vaccine along with phase II clinical trial reports. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial in the country.