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 21.09.2021 (through web-conferencing)

Sauli

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 21.09.2021 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	BIO/CT/21/000117 Dengue Tetravalent Vaccine, Live [CT]	M/s Panacea Biotec Limited	Firm presented its proposal for conduct of Phase III clinical trial of Dengue Tetravalent Vaccine, Live along with Phase I/II clinical trial report. After detailed deliberation, the committee recommended that the firm needs to clarify and revise the protocol as below for further consideration: 1. The definition for seroconversion should be revised by including the day at which it is assessed 2. Virological diagnosis of dengue should be defined 3. There seems error in calculating Sample Size. The same needs to be justified and rechecked. 4. Criteria for severity of the dengue infection should be specified 5. Number of cases of severe dengue cases requiring hospitalization and number of deaths must be included as secondary endpoints. Accordingly, the firm to submit revised protocol for further consideration.
2	BIO/CT/21/000133 Cholera Vaccine (Inactivated, Oral) [CT]	M/s Bharat Biotech International Limited	Firm presented its proposal for conduct of Phase III clinical trial of Cholera vaccine (Inactivated, Oral) along with Phase I/II clinical trial data generated at Bangladesh. After detailed deliberation, the committee recommended for grant of permission to conduct proposed Phase III clinical trial. Further, the committee recommended that the firm may explore the possibility of change in study design to double blind.
3	BIO/MA/21/000072	M/s Human Biologicals	Firm presented its proposal for grant

	Tetanus Vaccine (Adsorbed), IP [MA]	Limited	of permission to manufacture and market Tetanus Vaccine (Adsorbed), IP at Karkapatla Facility with waiver of clinical trial. The committee noted that the same Tetanus bulk and vaccine is already licensed to M/s Human Biologicals Limited at Gachibowli site. After detailed deliberation, the committee recommended for grant of marketing authorization permission for Tetanus Vaccine (Adsorbed), IP.
4	BIO/CT/21/000097 Measles and Rubella Vaccine, Live Attenuated (Freeze Dried) [CT]	M/s Biological E Limited	The Firm presented its proposal for conduct of Phase I clinical trial of Measles and Rubella Vaccine, Live Attenuated (Freeze Dried) along with animal toxicology data. The committee noted that MR vaccine is already marketed in the country. After detailed deliberation, the committee recommended for grant of approval for conduct of Phase I clinical trial.
5	BIO/CT/21/000135 Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (24 Valent) [CT]	M/s Biological E Limited	The Firm presented its proposal for conduct of Phase I clinical trial of Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) (24 Valent) along with animal toxicology data. After detailed deliberation, the committee recommended for grant of approval for conduct of Phase I clinical trial.
6	BIO/CT/21/000130 Typhoid Vi Conjugate Vaccine IP [CT]	M/s Cadila Healthcare Limited	Firm presented its proposal for conduct of active post marketing surveillance study. After detailed deliberation, the committee recommended for grant of approval for proposed study subject to the conditions under the Rules.