

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 21.02.2022 (through web-conferencing)

The Recommendations:

The SEC (Vaccine) deliberated the proposals on 21.02.2022 and recommended the following:

Sr. No.	File no. & Name of Vaccine	Name of Firm	Recommendations
1	GCT/PostAppr/2021/1281 8 Unadjuvanted RSV Maternal Vaccine (GCT)	M/s GSK Pharmaceuticals	Firm presented its proposal for Phase III global clinical trial protocol amendment (India as a participating country) of Respiratory syncytial virus (RSV) Maternal Vaccine before the committee. After detailed deliberation, the committee recommended for proposed Phase III clinical trial protocol amendment 2 dated 23 Jun 2021.
2	BIO/IMP/20/000092 MMR Vaccine (PI Update)	M/s GSK Pharmaceuticals	Firm presented its proposal for amendment in indication of Marketing Authorization (MA) permission of MMR Vaccine before the committee. After detailed deliberation, the committee recommended for amendment in indication to include population with ages 2 years or older and for immunocompromised persons living with HIV.
3	BIO/IMP/20/000095 Varicella vaccine (PI Update)	M/s GSK Pharmaceuticals	Firm presented its proposal for amendment in indication of Marketing Authorization permission of Varicella vaccine before the committee. The Committee noted that the proposed amendment was already approved earlier. After detailed deliberation, the committee recommended for proposed amendment in indication.
4	BIO/MA/21/000121 Pentavalent vaccine (MA)	M/s Panacea Biotec., Ltd.	Firm presented its proposal for grant of marketing authorization along with Phase II/III clinical trial report of Diphtheria, Tetanus, Pertussis, Poliomyelitis (Inactivated) and Haemophilus influenzae Type b Conjugate Vaccine I.P. before the committee. After detailed deliberation, the committee recommended for grant of approval to the vaccine.
5	BIO/CT/21/000147	M/s VHB Life	Firm presented its proposal for conduct of Phase III clinical trial of imported Varicella

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	Varicella Vaccine Live Attenuated IP (CT)	Sciences Ltd.	Vaccine Live Attenuated IP before the committee. After detailed deliberation, the committee recommended for the conduct of proposed Phase III trial with the condition that firm should define positive seroconversion in the study protocol. Accordingly, the firm shall submit the revised protocol to CDSCO for approval.
6	BIO/IMP/21/000004 Tetravalent Dengue Vaccine (Serotype 1, 2, 3 & 4) (Live Attenuated) (MA)	M/s Sanofi Healthcare India Pvt. Ltd.	In continuation to recommendations of SEC (Vaccine) meeting held on 02.07.2021, firm presented its proposal for permission to Import Dengue Tetravalent Vaccine (Live, Attenuated) (Serotypes 1, 2, 3 and 4) with the safety, immunogenicity and efficacy clinical trial including safety and immunogenicity data of Phase II trial conducted in the country and ICMR serosurvey study before the committee. Further, it was also stated that the Vaccine is prequalified by WHO in > 9 years to 45 year's age group on 25.03.2020 and EMA in 6 to 45 year's age including US, UK, Australia, Brazil, etc. The Committee noted that the firm has submitted additional details of the ICMR serosurvey study. After detailed deliberation, the committee recommended for grant of permission to import Tetravalent Dengue Vaccine (Serotype 1, 2, 3 & 4) (Live Attenuated) in 6 to 45 years age group without conduct of Phase III trial for the indication of prevention of dengue disease caused by Dengue virus serotypes 1,2,3 and 4 in individuals of in 6 to 45 years age group with test-confirmed previous dengue infection with the following conditions: 1. Mandatory screening for Dengue should be carried out before vaccination and the vaccine should not be administered in seronegative population. 2. The condition of screening should be conspicuous in the prescribing

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			<p>information/PI and should be mentioned on the label of the vial and outer carton.</p> <p>Dr. A. P. Dubey did not participate in the deliberation.</p>
7	<p>BIO/MA/21/000147</p> <p>Measles and Rubella Vaccine (Live) I.P.</p> <p>(MA)</p>	<p>M/s Indian Immunological Ltd.</p>	<p>Firm presented its proposal for marketing authorization permission proposal along Phase II/III clinical trial report of Measles and Rubella Vaccine (Live) I.P. before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of marketing approval to the vaccine.</p>
8	<p>BIO/CT/22/000006</p> <p>13-valent Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P.</p> <p>(CT)</p>	<p>M/s G. C. Chemie Pharmie Ltd.</p>	<p>Firm presented its proposal for conduct of Phase III clinical trial of 13-valent Pneumococcal Polysaccharide Conjugate Vaccine (Adsorbed) I.P. before the committee.</p> <p>After detailed deliberation, the committee recommended for the conduct of proposed Phase III clinical trial subject to the following conditions:</p> <ol style="list-style-type: none"> 1. OPA titre should be tested for all subjects. 2. The firm should proceed for administration of the booster dose after submitting the safety and immunogenicity data from primary vaccination series and after obtaining approval from the CDSCO. <p>Accordingly, the firm shall submit the revised protocol to CDSCO for approval</p>
9	<p>BIO/CT/20/000056</p> <p>Quadrivalent Inactivated Influenza vaccine (VLP)</p> <p>(CT protocol Amendment)</p>	<p>M/s Cadila Pharmaceuticals Ltd.</p>	<p>Firm presented its proposal for amendment in Phase III trial protocol of Quadrivalent Inactivated Influenza vaccine (VLP) before the committee.</p> <p>After detailed deliberation, the committee recommended for proposed amendment in Phase III trial protocol.</p>