

**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 02.07.2021 (through web-conferencing)**

**The Recommendations:**

The SEC (Vaccine) deliberated the proposals on 02.07.2021 and recommended the following:

| <b>Sr. No.</b> | <b>File no. &amp; Name of Vaccine</b>                                                                                          | <b>Name of Firm</b>                         | <b>Recommendations</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------|--------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1              | BIO/MA/18/000004<br>Diphtheria, Tetanus, Pertussis (Whole Cell) and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed) | M/s Bharat Biotech International Limited    | Firm requested time for making the presentation. Therefore, the proposal is deferred.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2              | BIO/MA/21/000030<br>Typhoid Vi Conjugate Vaccine, Typhoid Vi Conjugate Vaccine                                                 | M/s Bharat Biotech International Limited    | <p>Firm presented its proposal for grant of Marketing authorization of Typhoid Vi Conjugate Vaccine with the additional source of TT bulk used for conjugation.</p> <p>The committee noted that, the Typhoid Vi Conjugate Vaccine is already approved for marketing in the country with the same carrier from another source.</p> <p>After detailed deliberation, the committee recommended for the proposed addition of source for TT.</p>                                                                                                                                                             |
| 3              | BIO/IMP/21/000004<br><br>Tetravalent Dengue Vaccine (Serotype 1, 2, 3 & 4) (Live, Attenuated)<br><br>MA                        | M/s Sanofi Healthcare India Private Limited | <p>Firm presented its proposal for grant of Marketing authorization of Tetravalent Dengue Vaccine (Serotype 1, 2, 3 &amp; 4) (Live, Attenuated) along with safety and immunogenicity data from Phase-II clinical trial in the country and the efficacy results from studies from other countries.</p> <p>The committee noted that the vaccine is approved in US and other countries for use in test confirmed previous dengue infection in endemic areas. Further, the test to confirm previous dengue infection is currently not available in the country.</p> <p>After detailed deliberation, the</p> |

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|   |                                                                      |                                                    | <p>committee recommended that the firm should identify the endemic areas based on ICMR serosurvey and also present full details of the claims of the manufacturer of the diagnostic test for identification of previous dengue infection for further consideration.</p> <p>Dr. A. P. Dubey did not participate in the deliberation.</p>                                                                                                             |
| 4 | BIO/CT/21/000048<br>Hepatitis A (Live)<br>Vaccine, Freeze-dried      | M/s Joint Force<br>Pharmachem Pvt.<br>Ltd., Mumbai | <p>Firm presented its proposal for conduct of Phase III clinical trial of Hepatitis A (Live) Vaccine, Freeze-dried.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial subject to the condition that the firm should enroll subjects aged more than 18 months only.</p>                                                                                                                     |
| 5 | BIO/MA/19/000011<br>Measles, MR & MMR<br>Vaccine                     | M/s Serum Inst. of<br>India Private Limited        | <p>Firm presented its proposal for approval of the package insert mentioning co-administration of the Measles, MR &amp; MMR Vaccines with other vaccines.</p> <p>After detailed deliberation, the committee recommended wherever the firm claims concomitant administration of the Measles, MR &amp; MMR Vaccines along with other vaccine, the firm should mention the reference of the published literature based on which the claim is made.</p> |
| 6 | BIO/CT/21/000057<br><br>Inactivated Salk Polio<br>Vaccine (Adsorbed) | M/s Serum Inst. of<br>India Private Limited        | <p>Firm presented its proposal for conduct of Phase II/III clinical trial of Reduced Inactivated Salk Polio Vaccine (Adsorbed).</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct clinical trial subject to the condition that the clinical trial sites for both IPV vaccines studies should be separate and the interim results of phase II should be presented before</p>                          |

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|   |                                                                               |                                          | proceeding to Phase III study.                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 7 | BIO/CT/21/000046<br>Hexavalent [DTwP-HepB-Reduced IPV-Hib vaccine (Adsorbed)] | M/s Serum Inst. of India Private Limited | <p>Firm presented its proposal for conduct of Phase III clinical trial of Hexavalent [DTwP-HepB-Reduced IPV-Hib vaccine (Adsorbed)].</p> <p>After detailed deliberation, the committee recommended for the grant of permission to conduct the Phase III clinical trial.</p>                                                                                                                                                                     |
| 8 | BIO/MA/21/000041<br><br>Measles Vaccine, Live, IP (Attenuated, Freeze dried)  | M/s Biological E Limited                 | <p>Firm presented its proposal for grant of marketing authorization with local clinical trial waiver. The firm further stated that the vaccine is for export purpose only.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing the vaccine for export purpose only.</p>                                                                                                                     |
| 9 | BIO/IMP/21/000021<br>Inactivated Influenza Vaccine (Split Virion) IP          | M/s GSK Pharmaceuticals Limited          | <p>Firm presented its proposal for grant of marketing authorization for extended age group with local clinical trial waiver.</p> <p>After detailed deliberation, the committee recommended that permission may be granted for ages &gt;64 years subject to the condition that the firm should conduct Phase IV clinical trial in the country.</p> <p>Accordingly, the firm should submit the Phase IV clinical trial protocol for approval.</p> |