

**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 14.12.2023 and 15.12.2023 (through web-conferencing)**

**The Recommendations:**

The SEC (Vaccine) deliberated the proposals on 14.12.2023 and 15.12.2023 and recommended the following:

| Sr. No.                   | Name of Vaccine & File no.   | Name of Firm                                 | Recommendations  |
|---------------------------|--|--|--|
| <b>Day 1 (14.12.2023)</b> |  |  |  |
| 1                         | <p>Yellow Fever Vaccine (Live) (I.P)</p> <p>[Phase II/III clinical trial (re-deliberation)]</p> <p>[BIO/CT/22/000153]</p>  | <p>M/s Serum Institute of India Pvt. Ltd</p> | <p>In light of the recommendation of SEC meeting dated 21.02.2023 and 18.07.2023, the firm presented the revised Phase II/III clinical trial protocol of Yellow Fever Vaccine (Live) (I.P).</p> <p>After detailed deliberation, the committee recommended for approval to conduct Phase II/III clinical trial as per presented protocol with conditions that</p> <p>1) Firm should submit Phase II study report along with DSMB review for approval before initiation of Phase III.</p> <p>2) Adverse events of special interest (AESI) of Yellow Fever vaccine to be included in the Patient information sheet.</p> |
| 2                         | <p>Diphtheria Toxoid, Tetanus Toxoid, Pertussis (Whole cell), Hepatitis B, Reduced Poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate Vaccine (Adsorbed).</p> <p>[Phase – III clinical trial Protocol Amendment (SIWHEXA/IN-03 Version: 2.0 dated: 29 Aug. 2023)]</p> <p>[BIO/CT/21/000046]</p> | <p>M/s Serum Institute of India Pvt. Ltd</p> | <p>This office has granted permission on 21.11.2022 to conduct Phase III clinical trial of Diphtheria Toxoid, Tetanus Toxoid, Pertussis (Whole cell), Hepatitis B, Reduced Poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate Vaccine (Adsorbed).</p> <p>Now, the firm has submitted its proposal for the amendments in the approved Phase III clinical trial</p>   |

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|   |  |  | <p>protocol of Diphtheria Toxoid, Tetanus Toxoid, Pertussis (Whole cell), Hepatitis B, Reduced Poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate Vaccine (Adsorbed).</p> <p>After detailed deliberation, the committee recommended for protocol amendments as presented by the firm.</p>   |
| 3 | <p>13 Valent Pneumococcal Conjugate Vaccine.</p> <p>[Phase III clinical trial protocol]</p> <p>[BIO/CT/23/000101]</p>  | M/s. Novo Medi Lifesciences Ltd.       | <p>In light of the recommendation of SEC meeting dated 31.10.2023, the firm presented the revised Phase III clinical trial protocol of 13 Valent Pneumococcal Conjugate Vaccine.</p> <p>After detailed deliberation, the committee recommended for approval of the protocol as presented.</p>  |
| 4 | <p>13 valent Pneumococcal Conjugate Vaccine.</p> <p>[Import Permission]</p> <p>[BIO/IMP/22/000039]</p>   | M/s GC Chemie                          | <p>The firm presented its proposal for grant of import permission for 13 valent Pneumococcal Conjugate Vaccine along with Phase III clinical trial report.</p> <p>After detailed deliberation, the committee noted the results of Phase III clinical trial and recommended for approval of the vaccine for primary series of immunization (3 + 0).</p> |
| 5 | <p>Diphtheria, Tetanus, Pertussis (Whole cell), Hepatitis B (rDNA), inactivated Poliomyelitis and Haemophilus influenzae Type b Conjugate Vaccine (Adsorbed)</p> | M/s. Biological E. Limited, Telangana. | <p>Firm presented its proposal for conduct of Phase II clinical trial in 6-8 weeks old infants along with Phase I clinical trial report.</p> <p>After detailed deliberation, the committee noted the results of</p>  |

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|                           | [Phase-II clinical trial protocol]<br><br>[BIO/CT/23/000127]  |  | Phase I clinical trial report and recommended for grant of permission to conduct Phase-II clinical trial as per protocol presented.  |
| <b>Day 2 (15.12.2023)</b> |   |  |  |
| 1                         | Rotavirus Vaccine (Live Attenuated, Oral)<br><br>[Manufacturing permission]<br><br>[BIO/MA/23/000068] | M/s Bharat Biotech Limited,<br>Hyderabad | The firm presented its proposal for grant of manufacturing permission of Rotavirus Vaccine (Live Attenuated, Oral) (antibiotic free).<br><br>After detailed deliberation, the committee recommended for grant of manufacturing permission of Rotavirus Vaccine (Live Attenuated, Oral) (antibiotic free).  |
| 2                         | Varicella Vaccine Live Attenuated<br><br>[Import permission]<br><br>[BIO/IMP/21/000003]               | M/s VHB Lifesciences                     | The firm presented its proposal for grant of import permission of Varicella Vaccine Live Attenuated along with Phase III clinical trial report.<br><br>After detailed deliberation, the committee observed that immunogenicity of the vaccine is reported to be only 25.56% with respect to seroconversion as defined in the protocol.<br><br>In view of above, the committee is of the opinion that the reported immunogenicity result of the vaccine is not adequate in terms of vaccine efficacy. Therefore, the committee did not recommend for approval of the vaccine.<br><br>Further, the committee recommended for inspection of the |

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|   |   |   | Clinical trial sites and Central laboratory where the vaccines were tested for immunogenicity.   |
| 3 | Typhoid Vi Conjugate Vaccine<br>[Phase-IV clinical trial report<br>(re-deliberation)]<br>[BIO/CT/20/000044]   | M/s Zydus<br>Lifesciences Ltd               | In light of the recommendation of SEC meeting dated 18.07.2023, the firm presented the Phase-IV clinical trial report.<br>After detailed deliberation, the committee noted the results of Phase IV clinical trial.   |
| 4 | Herpes Zoster Vaccine<br>(Recombinant, Adjuvanated)<br>[Brand Name: Shingrix]<br>[Phase-III clinical trial report]<br>[BIO/CT/21/000084]  | M/s. GSK<br>Pharmaceuticals<br>Limited      | In light of the recommendation of SEC meeting dated 24.01.2023, the firm presented Phase III clinical trial report of Herpes Zoster Vaccine (Recombinant, Adjuvanated) in compliance with the condition of import permission.<br><br>After detailed deliberation, the committee noted the results of Phase III clinical trial. |
| 5 | Respiratory Syncytial Virus (RSV) Maternal (RSVPreF3) Vaccine.<br>[Protocol Amendment 02 dated 21st –June-2023 Protocol No. 219510 (RSV-MAT-015)]<br>[GCT/PostAppr/2023/28352]                          | M/s. GSK Pharma<br>India Private<br>Limited | The firm presented its protocol amendment 02 dated 21 June 2023, protocol no. 219510 (RSV-MAT-015).<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm  |
| 6 | ExPEC9V in the Prevention of Invasive Extraintestinal Pathogenic Escherichia coli Disease.<br>[Protocol amendment 6 dated 20 July 2023 study Protocol No: VAC52416BAC3001]<br>[GCT/PostAppr/2023/28580] | M/s PRA                                     | The firm presented its protocol amendment 06 dated 20 July 2023, protocol no. VAC52416BAC3001<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.   |