**Minutes of the Meeting of Special Subject Expert Committee (SEC) – Vaccine held on 15.10.2025 (through virtual mode) to review proposal for r-BCG Vaccine and advice Drugs Controller General (India)**

**The Recommendations:**

The Special SEC (Vaccine) deliberated the proposal on 15.10.2025 and recommended the following:

| Sr. No. | Name of Vaccine / Antisera & File no. | Name of Firm | Recommendations |
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| 1 | Recombinant BCG (rBCG) Vaccine for Tuberculosis (Freeze Dried)<br><br>BIO/MA/25/000087<br><br>(Marketing Authorization) | M/s Serum Institute of India Pvt. Ltd. | The firm presented the excerpts of following clinical study reports :-<br><br>**Study 1:** A multicenter phase II/III double blind, randomized, placebo controlled study to evaluate the efficacy and safety of VPM1002 in the prevention of tuberculosis (TB) recurrence in pulmonary TB patients after successful TB treatment in India [Protocol no.VPM1002-IN-3.01TBR, Version 2.0, dated 10.12.2016]<br><br>**Study 2:** A Phase III, Randomized, Double-blind, Three arm Placebo controlled Trial to Evaluate the Efficacy and Safety of two vaccines VPM1002 (rBCG of M/s Serum Institute) and Immuvac (M*w*) of M/s Cadila in Preventing Tuberculosis (TB) in Healthy Household Contacts of Newly Diagnosed Sputum Positive Pulmonary TB Patients [Protocol No. ICMR/ITRC/VAC/001/2018]<br><br>During deliberation, the committee made the following observations:-<br><br>1. Firm has submitted an application for grant of new drug permission for manufacturing of Recombinant BCG (rBCG) Vaccine for Tuberculosis (Freeze Dried) for following indications: 1. Active immunization for prevention of extra-pulmonary tuberculosis in individuals aged 6 years and above. 2. Active immunization for prevention of pulmonary |

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| | | | tuberculosis in individuals aged 6 to 18 years along with above mentioned study reports.<br><br>2. In Study 1, the difference of efficacy end points between the study vaccine and the placebo group for all TB recurrence cases (Bacteriologically Confirmed + Clinically diagnosed) and Bacteriologically Confirmed TB Recurrence cases (Symptomatic + Asymptomatic) were found to be not statistically significant, 13.5% and 7.8% respectively as per the presented post-hoc analysis data.<br><br>3. Similar results were also inferred from the post-hoc age sub-group analysis data.<br><br>4. The primary objective of the study 1 was to evaluate the efficacy of VPM1002 in prevention of TB recurrence and the study was concluded stating that the study vaccine failed to meet the primary endpoint of reduction in bacteriologically confirmed TB recurrence.<br><br>5. Further, the objective and end point of the study 1 is not related to the claimed indications in the present application and the firm did not draw any inference from the study 1 for the same.<br><br>6. In study 2, the firm has conducted subgroup analysis of primary and secondary endpoints of Phase III clinical trial conducted by ICMR for the claimed indications in new drug application. |

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| | | | 7. The primary objective of the study was to evaluate the efficacy of VPM 1002 by comparing the reduction and incidence of TB over 3-year period among Indian healthy household contacts of newly diagnosed sputum positive PTB patients vaccinated with VPM1002 in comparison to placebo and the primary end point of the study was to compare the percentage of confirmed TB cases (PTB and ETPB) as per NTEP guidelines in the vaccinated and placebo groups from two months after first dose of vaccine till 38 months follow-up period.<br><br>8. The vaccine efficacy against microbiologically confirmed EPTB (PP population) was concluded as 50.4% (VPM1002 – 12 and Placebo – 24) on the basis of primary endpoints of the ICMR study. However, the overall vaccine efficacy against all microbiologically confirmed TB (PTB and EPTB) was found to be 16.9% (VPM1002 – 73 and Placebo – 88), which was statistically non-significant as per same primary endpoint.<br><br>9. The statistically non-significant result was interpreted and concluded as statistically significant based on the calculation of the two arm data instead of three arm data of the ICMR study.<br><br>10. The primary objective of the study was not met and firm has not drawn any inference from the same. |

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| | | | 11. Further, in the ICMR study, the difference of efficacy in secondary end points between the study vaccine and the placebo group for the microbiologically confirmed, Clinical / Microbiologically diagnosed, Clinical / Microbiologically confirmed in the intended age groups for both PTB and EPTB were shown to be statistically significant as per the presented post-hoc analysis data with Haldane modification, while the overall result was statistically non-significant without post-hoc analysis and Haldane modification.<br><br>In view of above observations, the committee deliberated the proposal extensively and recommended that the study data with post hoc analysis was not adequate and conclusive to take considered decision for the new drug application. The firm should plan adequately powered study based on the outcome of secondary endpoint of ICMR study for conclusive decision.<br><br>***[Note:***<br><br>*Conflict of interest declared by the experts 1. Prof (Dr.) Urvashi B Singh, Dy. DG (TB), CTB Division, MoHFW, New Delhi 2. Dr. Srinath Satyanarayana, Director, ICMR-NIRT, 3. Prof. R. M. Pandey, Ex-HOD Biostatistics, AIIMS, New Delhi and 4. Dr. Sonali Sarkar, Professor, Preventive and Social Medicine, JIPMER.]* |