**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 14.09.2023(through web-conferencing)**

**The Recommendations:**

The SEC (Vaccine) deliberated the proposals on 14.09.2023 and recommended the following:

| Sr. No. | File no. & Name of Vaccine | Name of Firm | Recommendations |
|---|---|---|---|
| 1 | Varicella-Zoster Virus (VZV) vaccine<br>[Phase I CT (Re-deliberation)]<br>[BIO/CT/23/000027] | M/s Cadila Pharmaceuticals Limited | In light of the recommendation of SEC (vaccine) meeting dated 16.05.2023 and 18.07.2023, the firm presented the revised Phase I clinical trial protocol for grant of permission to conduct Phase I clinical trial for Varicella-Zoster Virus (VZV) vaccine.<br><br>After detailed deliberation, the committee recommended for grant of permission to conduct Phase-I clinical trial as per the presented protocol. |
| 2 | Inactivated Japanese Encephalitis vaccine (JENVAC®)<br>[Phase III CT Protocol (Re-deliberation)]<br>[BIO/CT/23/000060] | M/s Bharat Biotech International Limited | In light of the recommendation of SEC (vaccine) meeting dated 27.06.2023, firm presented the proposal for grant of permission to conduct Phase III clinical trial for Inactivated Japanese Encephalitis vaccine (JENVAC®) at age group of more than 1 year of age.<br><br>After detailed deliberation, the committee recommended to revise the protocol as below:-<br>1. Sero-prevalence study of the control group should be included as secondary objective.<br>2. Age stratification should be included in Group-II. (more than 50 years to 65 years and above 65 years)<br>3. No. of subjects in test group should be statistically |

| | | | |
|---|---|---|---|
| | | | calculated and revised.<br>4. Subjects who have been vaccinated with Seasonal flu vaccine in last one year and Typhoid Conjugate Vaccine should be mentioned in the exclusion criteria.<br>Accordingly, firm should submit the revised Phase III clinical trial Protocol for further deliberation. |
| 3 | 13-Valent Pneumococcal Conjugate Vaccine [Phase-IV CT Report] [BIO/CT/21/000159] | M/s Pfizer Ltd | Firm presented the Phase-IV clinical trial report of 13-Valent Pneumococcal Conjugate Vaccine.<br>After detailed deliberation, the committee noted the Phase IV clinical trial report of 13-Valent Pneumococcal Conjugate Vaccine. |
| 4 | 20-Valent Pneumococcal Conjugate Vaccine [CT Phase III] [CT/22/000015] | M/s Pfizer Ltd | In light of the recommendation of SEC (vaccine) meeting dated 26.04.2022, the firm presented revised Phase III clinical study Protocol no. B7471024, protocol amendment 1 dated 07 June 2023 .<br>After detailed deliberation, the committee recommended that sample size to be revised considering dropout rate and should be statistically powered.<br>Accordingly, firm should submit revised protocol for further deliberation by the committee. |
| 5 | Quadrivalent influenza vaccine (split-virion, inactivated) [PMS] [BIO/IMP/20/000066] | M/s Sanofi Healthcare Pvt Ltd | Firm presented the proposal for grant of permission for conduct of PMS study of Quadrivalent influenza vaccine (split-virion, inactivated).<br>After detailed deliberation, the committee recommended the PMS with condition to revise Informed Consent Form with list of solicited and unsolicited AEFI. |

| | | | |
|---|---|---|---|
| 6 | Diphtheria and Tetanus Vaccine (Adsorbed)<br>[CT Phase II interim safety report]<br>[BIO/CT/22/000022] | M/s. Panacea Biotec Ltd., | Firm presented Phase II interim safety report of Diphtheria and Tetanus Vaccine (Adsorbed) (Td) as per the condition of clinical trial permission.<br>After detailed deliberation, the committee noted the results of presented Phase II interim safety report and recommended to continue the study as per the approved protocol. |
| 7 | Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Recombinant Vaccine<br>[PAC]<br>[12-108/MSD/PAC-HPV/15-BD] | M/s MSD Pharmaceuticals Ltd | The proposal was deferred as per request of the firm. |
| 8 | Varicella Vaccine Live I.P<br>[PAC]<br>[12-30/MSD/PAC-Varicella/17-BD] | M/s MSD Pharmaceuticals Ltd | The proposal was deferred as per request of the firm. |