GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH RESEARCH

LOK SABHA
UNSTARRED QUESTION NO. 3085
TO BE ANSWERED ON 09th AUGUST, 2024

VACCINE FOR DENGUE

3085. SHRI SELVAGANAPATHI T.M.:

Will the Minister of **HEALTH AND FAMILY WELFARE** be pleased to state:

(a) whether the vaccine for dengue is likely to be available commercially as early as mid of 2026 in the country, if so, the details thereof;

(b) whether the trial of Phase I has been completed to ensure safety, if so, the details thereof;

(c) whether phases to test efficacy of the vaccine would start soon;

(d) if so, the details thereof;

(e) whether the vaccines for the Zika virus and the Kyasanur Forest Disease are also under progress; and

(f) if so, the details thereof?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI PRATAPRAO JADHAV)

(a) to (d): Indian Council of Medical Research (ICMR) has informed that it has signed an MoU with Panacea Biotec for a five year study titled "A Phase III, Multicenter, Randomized, Double -Blind, Placebo-Controlled Study to Evaluate the Efficacy, Immunogenicity and Safety of Single dose of Dengue Tetravalent Vaccine, Live Attenuated (Recombinant, Lyophilized) – "DengiAll" of Panacea Biotec Limited in Healthy Indian Adults." Panacea Biotec has earlier undertaken phases I/II clinical trials of the dengue vaccine in India. This recombinant vaccine has been developed by National Institutes of Health (NIH), USA and technology has been transferred to a number of companies across the world. The phase III clinical trial protocol has been approved by Drug Controller General of India (DCGI).

Department of Biotechnology (DBT) has informed that it has sanctioned a live Attenuated Tetravalent Dengue Vaccine candidate for Phase I clinical trial under the National Biopharma Mission.

Central Drugs Standard Control Organisation (CDSCO) has informed that it has granted permissions for conduct of clinical trials for dengue vaccines to four applicants. The grant of

approval to market vaccines depends upon submission of satisfactory chemical and pharmaceutical data, pre-clinical animal data and clinical trials data etc. as per the provisions of New Drugs and Clinical Trials Rules, 2019 under Drugs and Cosmetic Act, 1940.

(e) & (f): **Zika Vaccine: -** (i) ICMR has further informed that Bharat Biotech Ltd has developed a purified inactivated Zika viral vaccine candidate (BBV121). This vaccine formulation completed a Phase 1 clinical trial.

(ii) CDSCO has informed that it has granted clinical trial permission to conduct Phase IIa clinical trial of a Zika virus vaccine.

Kyasanur Forest Disease: - (i) For the development of vaccine candidate against Kyasanur Forest Disease (KFD), a joint Memorandum of Agreement (MoA) has been signed between Indian Council of Medical Research (ICMR), New Delhi & M/s Indian Immunological Ltd. (IIL), Hyderabad. Technology for development of inactivated virus based KFD vaccine has been transferred to the M/s IIL. Necessary approvals from International Board of Specialty Certification (IBSC), Institutional Animal Ethics Committee (IAEC) and Committee for Control and Supervision of Experiments on Animals (CPCSEA) have already been taken and the strain of KFD virus (NIV 164187) has been transferred. The production of KFD vaccine candidate at small scale has been achieved for pre-clinical studies.

(ii) Also, as informed by DBT, Institute of Biotechnology Research & Innovation Council (iBRIC) - Translational Health Science & Technology Institute (THSTI), Faridabad has been engaged in Research and Development (R&D) for KFD vaccine development.

(iii) CDSCO has informed that license has been granted for manufacturing of KFD Vaccine, Killed (For Human Use) to one applicant.

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