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

LOK SABHA UNSTARRED QUESTION NO. 2165 TO BE ANSWERED ON 01ST AUGUST, 2025

TRIAL OF DENGUE VACCINE

2165. DR. M P ABDUSSAMAD SAMADANI: SMT. D K ARUNA: SHRI EATALA RAJENDER:

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

- (a) whether enrolment of participants in third phase clinical trials led by Indian Council of Medical Research (ICMR) for India's first dengue vaccine is nearly complete and if so, the details thereof;
- (b) whether dengue is a major public health concern in the country which ranks among the top 30 countries with the highest incidence of the disease and if so, the details thereof along with the corrective steps being taken by the Government in this regard;
- (c) whether there is currently no antiviral treatment or licensed vaccine for dengue in the country and if so, details thereof;
- (d) whether the trial is likely to be rolled across 20 centres in the country;
- (e) if so, the results yielded till date along with the funds sanctioned, spent for Telangana and Karnataka;
- (f) whether all four serotypes of the dengue virus are known to circulate or co-circulate in many regions across the country; and
- (g) if so, the details thereof along with the measures undertaken by the Government to ensure that we have an effective vaccine that achieves good efficacy for all four serotypes of the said virus?

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

(a), (d) and (e): Indian Council of Medical Research (ICMR) has informed that it has undertaken a clinical trial 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". The trial involves over 10,000 participants, out of which more than 70 per cent enrolment has been completed. The trial has been implemented in 20 sites across India. There are two sites in Karnataka and one site in Telangana. These sites are: JSS Medical college and hospital, Mysore (Karnataka), Bangalore Medical College & Research Institute, Bengaluru (Karnataka) and All India Institute of Medical Sciences Bibinagar (Telangana). The approximate budget is 1.3 to 1.5 crore Rupees per site for the trial.

(b) (c) (f) and (g): As per the information provided by National Centre for Disease Control (NCDC), a total of 5,73,563 Laboratory confirmed (L form) Dengue cases were reported through Integrated Health Information Platform (IHIP) in the year 2024.

According to ICMR, all four serotypes of the dengue virus (DENV-1, DENV-2, DENV-3, and DENV -4) are known to circulate and co-circulate in India. Multiple serotypes can be present in the same geographical region and can even infect the same individual at the same time. Hence, participants have been enrolled in the ICMR vaccine trial from the different zones where these four serotypes circulate in order to test the efficacy of the vaccine against all four serotypes.

The Ministry of Health and Family Welfare, Director General of Health Services and National Center for Vector Borne Disease Control (NCVBDC) regularly monitor the situation of Dengue outbreaks across the country for assessing the disease situation, preparedness, technical guidance and to sensitize and forewarn the States. Under National Health Mission, adequate budgetary support is provided to States and Union Territories for Dengue control activities like epidemic preparedness, monitoring, case management, vector control (provision of domestic breeding checkers, ASHA involvement, insecticide, fogging machines), training, intersectoral convergence, awareness activities, etc. For surveillance and free of cost diagnosis of Dengue, Sentinel Surveillance Hospitals with laboratory facility and Apex Referral laboratories with advance diagnostic facilities have been identified across the country. As per Indian Council of Medical Research (ICMR), there is no specific antiviral treatment or licensed vaccines for dengue and the treatment is supportive in nature. Government of India has developed National guidelines on Dengue case treatment/management, in consultation with experts and shared with all States/UTs for implementation. The guidelines emphasize on the preparedness of hospitals for case treatment/management. In addition, advisories have been issued from time to time to States/UTs for prevention and control of dengue including case management.
