

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

**LOK SABHA
UNSTARRED QUESTION NO. 3514
TO BE ANSWERED ON 13TH MARCH, 2026**

TRIALS OF HPV VACCINATION

†3514. SHRI SUDHAKAR SINGH:

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

- (a) whether the Government has reviewed the HPV vaccination trials conducted in 2010 in Bihar, Andhra Pradesh, Gujarat and other States along with the recommendations contained in the 72nd Report of the Parliamentary Standing Committee and if so, the action taken thereon so far;
- (b) whether any independent inquiry or audit has been conducted into the terms, financial provisions, accountability mechanisms and data-security provisions of the Memorandum of Understanding (MoUs) signed by Bihar and other States with the Gates Foundation and PATH, if so, the details thereof;
- (c) whether a clear Standard Operating Procedure (SOP) is in place to ensure safety, informed consent, monitoring of adverse impacts and transparency in the HPV vaccination programme for girls aged 9-14 years, if so, the details thereof;
- (d) whether the Government is considering the constitution of an independent committee to review the said agreements and programmes; and
- (e) if so, the details thereof?

ANSWER

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

(a) to (e): The actions undertaken by the Ministry consequent to the recommendations of 72nd Report of the Department Related Parliamentary Standing Committee on Health and Family Welfare on HPV vaccine trials were taken into cognizance by the Committee as reflected in its 81st Report. Government has undertaken many health research regulatory reforms in the last decade, some major ones are mentioned below:

1. New Drugs and Clinical Trials Rules (NDCTR), 2019 introduced a comprehensive regulatory framework and streamlined approval processes for clinical trials and new drugs. The Rules also made it mandatory to register the Ethics Committees reviewing biomedical research with Department of Health Research (DHR).
2. DHR and Central Drugs Standard Control Organization (CDSCO) have set up the NAITIK Portal and SUGAM Portal for the online registration of all ethics committees in India. Their composition and functions are reviewed to ensure compliance with the ethical guidelines and regulations. Also, DCGI has mandated to prospectively register all clinical trial studies online on Portal of Clinical Trials Registry of India (CTRI), before enrolment of the first participant.

3. The scientific and ethical review mechanisms before trial initiation have been strengthened. Ethics Committees are required to ensure enhanced oversight, including careful review of research proposals to ensure that risks are minimized.

4. Indian Council of Medical Research (ICMR) updated National Ethical Guidelines for Biomedical and Health Research in 2017 setting forth the requirement to ensure prior scientific validity, robust ethics committee review, risk minimization strategies, safety monitoring and oversight and follow-up of participants to implement safeguards for the protection of research participants including vulnerable participants.

5. Standard Operating Procedures (SOPs) of Health Ministry's Screening Committee have been revised for adequately regulating international collaborations in health research.

Since Health is a state subject, the State Governments independently also undertake MoUs with national and international organizations on health-related matters.

The nationwide HPV vaccination campaign for girls aged 14 years in the country was launched on February 28, 2026. The preparatory work took into consideration the recommendation made by scientific bodies of the world including Strategic Advisory Group of Experts on Immunization (SAGE), World Health Organization (WHO), Indian Council of Medical Research (ICMR) and National Technical Advisory Group on Immunization (NTAGI). The rollout was preceded by careful deliberations, NTAGI guidance and extensive training of medical and paramedical staff across all 36 States/UTs in the country was taken.

The single-dose Gardasil-4 vaccine is administered free of cost at government health facilities, including Ayushman Arogya Mandirs- Primary Health Centres (PHCs), Community Health Centers (CHCs), Sub-District Hospitals (SDH)/District Hospitals (DHs) & Government Medical Colleges (GMCs). The vaccines are being administered in the presence of medical officers and the vaccination sites are linked to 24x7 Adverse Events Following Immunization (AEFI) Management Centers for prompt management of adverse events, if any. Parental consent is mandatory, and beneficiaries can register on the U-WIN platform. The vaccination is voluntary, and medical officers are trained to manage adverse events, if any. The operational guidelines for the roll out of HPV vaccination campaign have been disseminated to all States/UTs.
