

Universal Health Organisation (UHO)



22nd February 2026

To,
The Honourable Minister for Health and Family Welfare,
Government of Telangana,
Secretariat, Hyderabad – 500 022,
Telangana.

Subject: Urgent Caution Regarding the Proposed Statewide HPV Vaccination Programme – Demand for Prior Informed Consent, Ethical Compliance, and Robust Adverse Event Monitoring

Reference: Parliamentary Standing Committee on Health and Family Welfare Report on the HPV Vaccine Demonstration Project (Andhra Pradesh & Gujarat, 2009–10); Sama Resource Group for Women and Health Fact-Finding Report, Khammam, March 2010.

Honourable Minister,

We write to you with deep concern and a strong sense of civic duty on behalf of civil society organisations, health activists, parents, and citizens committed to the protection of the health and rights of adolescent girls in Telangana. It has come to our attention that the State Government is preparing to launch a statewide Human Papillomavirus (HPV) vaccination programme targeting adolescent girls, and is awaiting formal clearance from the Union Government to proceed. While we unequivocally support the goal of reducing the burden of cervical cancer, we are gravely concerned that the proposed rollout may proceed without adequate safeguards, in the shadow of a deeply troubled precedent established by the earlier HPV vaccine demonstration project conducted in undivided Andhra Pradesh and Gujarat between 2009 and 2010.

I. THE TROUBLED LEGACY OF THE PRIOR HPV DEMONSTRATION PROJECT

The HPV vaccine demonstration project conducted in Khammam district of Andhra Pradesh and Vadodara district of Gujarat in 2009–10, funded by the Bill & Melinda Gates Foundation and implemented through PATH (Program for Appropriate Technology in Health) in collaboration with the Indian Council of Medical Research (ICMR), was the subject of severe censure by the Parliamentary Standing Committee on Health and Family Welfare. The Committee characterised the project as a flawed, commercially driven trial that bypassed fundamental ethical norms and raised serious concerns about conflicts of interest involving PATH, ICMR, and the Foundation.

When the Sama Resource Group for Women and Health conducted a fact-finding mission in Khammam in March 2010, they documented that as many as 120 girls had experienced adverse

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reactions including epileptic seizures, severe stomach aches, persistent headaches, and mood swings following vaccination. The Sama report further documented cases of early onset of menstruation, heavy menstrual bleeding, and severe menstrual cramps in the aftermath of vaccination. Seven deaths were reported in connection with the project, though a direct causal link was not conclusively established. These findings represent a profound failure of duty of care to vulnerable children and demand that any future vaccination initiative be preceded by the most rigorous safeguards.

II. DOCUMENTED ETHICAL VIOLATIONS IN THE PRIOR PROJECT

The Parliamentary Standing Committee and independent investigators identified the following specific ethical violations in the earlier project, which must be explicitly addressed before any new programme commences:

1. **Improper Consent Procedures:** Consent was obtained from hostel wardens on behalf of girls rather than from parents or legal guardians, a practice that is wholly inconsistent with the ethical and legal requirements for informed consent in clinical research and public health interventions involving minors.
2. **Language Barrier in Consent Forms:** Consent forms were in English, which was neither the language of the participants nor their guardians. Meaningful, free, and informed consent cannot be obtained through instruments that participants cannot read or comprehend.
3. **Absence of Parental Notification:** Parents were neither informed nor consulted before their daughters received the vaccine. This constitutes a fundamental violation of the rights of the child and the obligations of the State towards families.
4. **Inadequate Adverse Event Monitoring:** There was no robust system in place to monitor, record, investigate, or respond to adverse events following immunisation. The girls who experienced severe reactions reportedly received little or no medical attention, and causality assessments were either absent or inadequate.
5. **Conflicts of Interest:** The Parliamentary Committee raised grave concerns about the overlapping financial interests of PATH, the Bill & Melinda Gates Foundation, and ICMR, and whether these interests unduly influenced the design and conduct of the project to the detriment of participants' welfare.

III. OUR DEMANDS: A RIGHTS-BASED, ETHICALLY SOUND FRAMEWORK FOR ANY FUTURE PROGRAMME

In light of the above, we respectfully but firmly urge Your Honour to ensure that the following conditions are met before any statewide HPV vaccination programme is launched in Telangana:

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A. Prior Informed Consent

Informed consent must be obtained directly from the parents or legal guardians of every minor girl proposed to be vaccinated. Consent forms must be prepared in Telugu and in simple, clear language that can be understood by persons with varying levels of literacy. Where parents are illiterate, trained health workers must explain the process verbally and in full, and an independent witness must attest to the voluntary nature of the consent. Consent by institutional authorities, wardens, or teachers must be explicitly prohibited. Girls who are minors must be given age-appropriate information about the vaccine and its purpose, and their assent must also be recorded alongside parental consent.

B. Voluntariness and Freedom from Coercion

Participation in the programme must be entirely voluntary. No girl or her family must face any direct or indirect pressure, inducement, or penalty for refusing vaccination. There must be no stigmatisation of or discrimination against those who opt out. Instructions to this effect must be issued clearly and unambiguously to all programme personnel, including health workers, school staff, and district officials.

C. Comprehensive Adverse Event Monitoring and Response

A transparent, well-resourced, and independent system for the surveillance, recording, investigation, and management of Adverse Events Following Immunisation (AEFI) must be established and fully operational before the programme commences. This system must include: (i) a 24-hour helpline accessible to parents, girls, and health workers; (ii) rapid response medical teams at the district level; (iii) mandatory reporting of all adverse events, however minor, to district and State AEFI committees; (iv) independent causality assessment by qualified medical experts not associated with the vaccine manufacturers or implementing agencies; and (v) prompt access to free medical care for all girls who experience adverse reactions. All AEFI data must be placed in the public domain on a monthly basis.

D. Independent Ethical Oversight

The programme must be overseen by an independent Ethics and Oversight Committee that includes medical ethicists, public health experts, representatives of women's and child rights organisations, and community members. This committee must have the authority to pause or halt the programme if safety concerns arise and must report publicly on a regular basis.

E. Transparency on Funding and Conflicts of Interest

Full public disclosure must be made of all funding sources for the programme, the roles and financial interests of all implementing agencies and partners, and any arrangements with vaccine manufacturers. Any agency or individual with a financial interest in the outcome of the programme must be excluded from roles in its governance or oversight.

F. Community Awareness and Social Mobilisation

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A sustained community awareness campaign in Telugu must precede and accompany the programme, providing evidence-based information about HPV, cervical cancer, the vaccine's benefits and known risks, the consent process, and the AEFI reporting mechanism. This campaign must reach not only parents and girls but also teachers, community leaders, and local elected representatives.

IV. SERIOUS CONCERNS ABOUT THE STATE'S PREPAREDNESS FOR THE PROPOSED ROLLOUT

Beyond the historical wrongs catalogued above, we are compelled to place on record our grave reservations about whether the State Government has, at this juncture, undertaken the groundwork that a programme of this scale and sensitivity demands. These are not peripheral procedural matters. They go to the very heart of the State's capacity and seriousness of purpose in discharging its duty of care to adolescent girls.

A. The Absence of a Telangana-Specific Epidemiological Basis

The State Government has not placed in the public domain any Telangana-specific epidemiological data or peer-reviewed case studies establishing the burden of cervical cancer among the population of girls who are proposed to be vaccinated. National aggregate figures, or data drawn from undivided Andhra Pradesh, cannot serve as the sole justification for a statewide programme targeting Telangana's adolescent girls. We are not aware of any systematic, published study that has examined the incidence and prevalence of HPV-related cervical cancer specifically within the current boundaries of Telangana, across its distinct districts and demographic groups. Before mass vaccination is sanctioned, the Government must commission or disclose a robust, district-level epidemiological assessment, peer-reviewed and publicly available, so that citizens, health professionals, and independent experts may evaluate whether the proposed intervention is proportionate, appropriately targeted, and consistent with the actual burden of disease in this State.

B. Opacity Surrounding Funding, Financial Arrangements, and Stakeholder Interests

It is deeply troubling that, at this advanced stage of planning, no public accounting has been made of the funding that has been made available or committed for the proposed HPV vaccination programme in Telangana. Citizens and civil society organisations have received no clarity on whether this programme is to be financed exclusively from State and Central government budgetary allocations, or whether external funding from private foundations, bilateral development agencies, or other non-governmental sources has been sought or accepted. The identity of all funding entities, the quantum of each contribution, and any conditions or expectations attached to such funding must be disclosed without reservation. Equally, the complete roster of implementing agencies, procurement partners, logistics providers, and technical advisors must be made public, along with a declaration of any

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financial or institutional interest these parties hold in the outcome of the programme. The disastrous conflicts of interest that corrupted the 2009–10 demonstration project must not be permitted to recur. Any budget approved or under discussion — whether at the State Cabinet level, the Department of Health, or through centrally sponsored scheme mechanisms — must be placed in the public domain in itemised form, including allocations for procurement, cold chain infrastructure, human resources, training, community awareness, and adverse event monitoring.

C. Unresolved Questions About the Adequacy of Training for Vaccination Personnel

The Government has not made available to the public any information establishing that the medical and paramedical staff deployed at designated vaccination sites have been adequately trained — in both the technical and the ethical dimensions of administering the HPV vaccine to adolescent girls. Training cannot be reduced to the mechanical act of administering an injection. It must encompass a thorough understanding of the vaccine’s contraindications, recognition of the early signs of anaphylaxis and other immediate adverse reactions, the proper protocols for post-vaccination observation, and the procedure for escalating and reporting adverse events. It must also cover the correct procedure for obtaining and documenting informed consent, communicating with parents and girls in an accessible and non-coercive manner, and understanding the rights of participants to refuse. The Government must disclose the content, duration, and reach of any training programme that has been or is proposed to be conducted, the agencies responsible for delivering such training, and the mechanism by which competency has been or will be assessed across all designated vaccination points.

D. Absence of Published Guidelines and Post-Vaccination Monitoring Protocols

No operational guidelines specific to the Telangana HPV vaccination programme have, to our knowledge, been issued or placed in the public domain. In their absence, there is no authoritative framework governing how vaccination sessions are to be conducted, how the post-vaccination observation period is to be managed, what constitutes a reportable adverse event, how such events are to be documented and escalated, and what immediate medical response is to be provided at the vaccination site. The silence on post-vaccination monitoring is particularly alarming. It is established clinical practice that vaccinated individuals must be observed for a minimum period following administration, and that sites must have the capacity to manage acute reactions including anaphylaxis. The Government must publish, in advance of any rollout, the specific Standard Operating Procedures for: (i) the management of the immediate post-vaccination period at each vaccination site; (ii) the recording and escalation of all adverse events, whether or not they appear to be causally related to the vaccine; (iii) the activation of rapid response mechanisms for serious adverse events; and (iv) the long-term follow-up of vaccinated girls across the full course of the immunisation schedule. Monitoring cannot be reduced to paperwork submitted after the fact. It requires a live, staffed, and

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well-resourced system that is accountable to the public, and whose data is disclosed transparently, regularly, and in a format that civil society and independent experts can scrutinise and act upon.

E. Cold Chain Infrastructure and Vaccine Handling Protocols

The Government has not demonstrated to the public that adequate vaccine preservation infrastructure is in place across all proposed vaccination sites in Telangana. HPV vaccines must be stored within a strictly maintained temperature range of 2°C to 8°C, and any deviation — during storage, transit, or at the point of administration — renders the vaccine ineffective and potentially harmful. The Government must disclose whether functional, verified refrigeration equipment is available at each designated site; whether dedicated vaccine carriers and cold boxes with sufficient ice packs are in place for transportation; whether clear written protocols govern the transfer and shifting of vaccine vials between storage facilities and vaccination points; what procedures are in place to detect and respond to cold chain failures; and who bears responsibility for certifying that the cold chain has been maintained before each vial is used. A vaccine stored in compromised conditions is not a safe vaccine. Silence on cold chain preparedness is not a technicality — it is a direct risk to the girls who will receive these doses.

F. Vaccine Composition, Dosing Per Vial, and Mandatory Disclosure of the Package Insert

Parents and guardians of adolescent girls who are proposed recipients of the HPV vaccine are entitled to know the precise composition of the vaccine that will be administered to their children. In particular, it is imperative that the Government disclose whether the vaccine preparation to be deployed in Telangana contains thimerosal (ethyl mercury), a preservative that has been the subject of significant scientific and public health debate, or any other adjuvant or excipient that may be of concern to parents, particularly those whose children have known allergies or sensitivities. The exact number of doses contained in each vial must also be clearly disclosed and verified, as multi-dose vials carry particular risks of contamination and dosing error when not handled in strict accordance with manufacturer specifications.

Equally, the manufacturer's package insert — the full prescribing information, including contraindications, precautions, known adverse reactions, and the population in whom the vaccine has and has not been studied — must be made available to parents in Telugu translation before consent is sought. This is not an optional courtesy; it is the minimum standard of informed consent. The Government must further confirm that the vaccine label and package insert, in both English and Telugu, will be prominently displayed at every vaccination centre, so that any parent, girl, or health worker who wishes to read it may do so freely and without obstruction.

G. Record-Keeping: Individual Vaccination Records and Vial Accountability

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A mass vaccination programme without scrupulous, individualised record-keeping is a programme without accountability. The Government must put in place and publicly describe a robust record-keeping system that captures, at a minimum, the full name, age, address, and school or institution of every girl vaccinated; the date, time, and location of vaccination; the name of the health worker who administered the dose; the batch number, manufacturer, and expiry date of the vial used; the dose number within the scheduled series; and the name and contact details of the parent or guardian who provided consent. These records must be maintained at the site, retained at the district level, and aggregated at the State level in a manner that allows individual follow-up in the event of an adverse event or an outbreak linked to a particular batch. Vial accountability — recording how many doses were drawn from each vial, to whom they were administered, and what happened to any unused doses — is equally essential to prevent wastage, over-dosing, contamination, and the falsification of coverage data. The Government must specify the format, custodian, retention period, and accessibility of these records, and must commit to making aggregated, anonymised data publicly available so that the programme can be independently audited.

These are not hypothetical or precautionary concerns conjured for the purpose of obstruction. They are the direct lessons of what went wrong in Khammam in 2010. A State that proceeds with a mass vaccination programme without having first resolved these fundamental questions of preparedness is not acting in the interest of the girls it proposes to protect. It is the obligation of this Government to demonstrate, through concrete, verifiable, and publicly disclosed action, that each of these gaps has been closed before a single dose is administered.

V. CLOSING APPEAL

We are acutely aware of the devastating toll that cervical cancer takes on women in India, disproportionately affecting those from marginalised communities. We seek only to ensure that the girls of Telangana are vaccinated with their full knowledge and that of their families, that they are treated with dignity and not as mere targets of a programme, and that any child who suffers harm receives prompt, compassionate, and effective medical care.

The history of the earlier project in Khammam is a sombre reminder that well-intentioned public health programmes can cause irreparable harm when ethical foundations are weak. The Government of Telangana has the opportunity to set a national standard for how HPV vaccination, and indeed all mass vaccination programmes, should be conducted in a democracy that respects the rights of its citizens.

We respectfully request an urgent meeting with Your Honour and the senior officials of the Department of Health and Family Welfare to discuss the concerns raised in this letter and to receive

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assurances that the programme will proceed only within a robust ethical and rights-based framework. We are available at your convenience and stand ready to assist in building a programme that is safe, ethical, and truly beneficial to the girls and women of Telangana.

We thank Your Honour for your time and attention to this matter of the highest urgency.

Yours faithfully,

Dr Amitav Banerjee (Chairperson, UHO),
On behalf of Managing Committee of Universal Health Organisation.

Dr. Narasimha Reddy Donthi
Dr. Sujata Mittal, Gynec Oncologist

CC:

The Chief Minister, Government of Telangana
The Principal Secretary, Health and Family Welfare Department, Government of Telangana
The Director of Public Health and Family Welfare, Telangana
The National Human Rights Commission, New Delhi
The Union Minister for Health and Family Welfare, Government of India