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Subject: Concerns around the rollout of the human papillomavirus (HPV) vaccine and demand for an immediate halt

Respected Shri Mansukh Mandaviya,

We are writing to bring to your attention some serious concerns regarding the ongoing rollout of the human papillomavirus (HPV) vaccine in India. As the Union Minister for Health and Family Welfare, your role in safeguarding the health and well-being of our citizens is crucial, and we believe it is essential to address these concerns promptly.

Introduction:

Human Papillomavirus (HPV) is a sexually transmitted virus with more than 200 subtypes (out of which about 100 are considered to be sexually transmitted), some of which can lead to cervical inflammation and, may eventually lead to cervical cancer due to multiple other factors. However, in most cases the infections are harmless and go away without treatment. The body's own defence system eliminates the virus. Recent scientific studies and publications have raised significant doubts about the efficacy and safety of the HPV vaccine currently being administered.

Lack of Evidence on causes and prevention of Cervical Cancer:

Clinical trials have failed to provide conclusive evidence that the HPV vaccine effectively prevents cervical cancer¹. At the same time serious adverse reactions are common. Below are some points to consider:

- Most HPV infections are asymptomatic and resolve spontaneously.
- 200 HPV types have so far been identified. Among them, Type 16 HPV is supposed to pose the highest risk for cervix infection that may lead to cervix cancer due to multiple

¹ [Will HPV vaccination prevent cervical cancer? - Claire P Rees, Petra Brhlikova, Allyson M Pollock, 2020 \(sagepub.com\)](#)



other factors, followed by Type 18. The subtypes 16 and 18 account for 70% of the cases of cervix infection. HPV subtypes 6 and 11 can lead to genital warts.

- There is lack of conclusive data regarding the length of immunologic protection the vaccine confers against HPV subtypes 16 and 18. Studies so far have followed up with the vaccinated ‘subjects’ for 5 years and have shown that it offers protection only for 5 years. The long-term efficacy and protection by the vaccine is unknown.
- The lifetime risk of an incident of HPV infection is 79%; most HPV infections are transient and 67% clear within one year. Around 10% of women without CIN have HPV infection at any one time. The mechanism of progression from HPV infection to cervical cancer and its precursors is not well understood.
- In India, the age-standardized incidence rate is 14.7 per 100,000 women, and the age-standardized mortality rate is 9.2 per 100,000 women.” (0.0147% and 0.0092%) For this incidence at 55 to 59 years of age taking the risk of having 1% serious adverse events at 9 to 15 years of age, which serious events not even mentioned in the trial paper, is not advisable
- There are no well-designed studies done to prove vaccine efficacy for anal, penile, vaginal, vulvar, and oropharyngeal cancers.
- Virus alone not proven to be causative agent. Use of Oral Contraceptive pills for longer duration had definite higher risk for developing cervical cancer². Early sexual contact, alcohol, smoking etc. are risk factors for cervical cancer.³

Serious Adverse Reactions:

The HPV vaccine has been associated with serious adverse events, including autoimmune disorders, multiple sclerosis, Guillain-Barré syndrome, paralysis, chronic fatigue syndrome, and even death. Malfunctions of the autonomic nervous system, cognitive dysfunctions, gait disturbances, menstrual problems and ovarian failure have all been reported following HPV vaccination as well⁴.

Young teenage girls have no risk of dying from cervical cancer but they gamble with permanently disabling autoimmune or degenerative disorders, or death, following their HPV vaccines. In fact, the HPV vaccine may enhance cervical disease in young women with pre-existing HPV infections.

The Federal Vaccine Adverse Event Reporting System (VAERS) in the US has logged a total of 12,424 of adverse events following HPV vaccination, according to the US Centre for Disease Control and Prevention. Between June 2006 through December 2008, more than 23 million doses were administered in the US alone. Of these, 772 were reports of serious events (6.2 % of the reports) including 32 deaths.

Indian Health ministry officials shelved bringing HPV Vaccine under Universal Immunisation Programme mainly due to reasons related to concerns around side-effects.

India's HPV Vaccine Trials:

² <https://sci-hub.se/https://doi.org/10.1016/j.ejogrb.2020.02.014>

³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4404964/>

⁴ [Microsoft Word - 1.26.16 - New Concerns about the HPV vaccine.docx \(acpeds.org\)](#)



The trials conducted by PATH, backed by the Bill and Melinda Gates Foundation, in Andhra Pradesh and Gujarat raised alarming issues, including seven reported deaths among vaccinated girls with no prior illnesses⁵. PATH described it as an observational study instead of a formal clinical trial presumably to circumvent thorny ethical issues. This tragedy on tribal girls was investigated by the Parliamentary Standing Committee on Health and Family Welfare and it submitted the 72nd Report – Alleged Irregularities in the Conduct of studies using human papilloma virus vaccine (HPV) by PATH in India. Despite recommendations from the Parliamentary Standing Committee for a thorough investigation, no such inquiry has taken place, leaving the safety of the vaccine in question.

Cervavac - Product Disclosure, Trials, and Approvals:

The product disclosure for Cervavac indicates limitations in protection, lack of demonstrated efficacy against all HPV types, and the vaccine not being an alternative to routine screening⁶. Moreover, the trial details and reported side effects raise concerns about the vaccine's overall safety and long-term effects.

The Summary of Product Characteristics of Cervavac mention the following:

- Vaccination will not result in protection in all vaccine recipients.
- It is only for prophylactic use and has no effect on active infections.
- CERVAVAC® has not been demonstrated to protect against diseases due to HPV types not contained in the vaccine
- The vaccine is not an alternative to routine screening

Concerns over Cervavac trials

The concerns over the Cervavac trials are multi-faceted, raising significant doubts about the comprehensiveness and reliability of the study⁷.

- Firstly, the trial's duration of only seven months raises questions about the potential long-term side effects of the vaccine that may not have been adequately assessed during this relatively short timeframe.
- The trial exclusively focused on healthy girls, limiting the generalizability of the findings to a broader population.
- There is uncertainty about whether proper approval was obtained from an ethics committee, highlighting potential ethical considerations in the trial.
- Additionally, the decision to conduct trials directly on children without prior testing on adults raises concerns about the vaccine's safety and efficacy.
- The study's lack of a placebo group, with the comparison against Gardasil, raises questions about the accurate assessment of Cervavac's adverse events, potentially overlooking known issues associated with Gardasil.
- Importantly, the study failed to investigate the effects of the vaccine on fertility⁸, a critical aspect that should be thoroughly examined.

⁵ [Trials and tribulations: an expose of the HPV vaccine trials by the 72nd Parliamentary Standing Committee Report – Sama \(samawomenshealth.in\)](https://www.samawomenshealth.in)

⁶ [gHPV - SmPC 2022.pdf \(cdsco.gov.in\)](https://www.cdsco.gov.in)

⁷ [Immunogenicity and safety of a new quadrivalent HPV vaccine in girls and boys aged 9–14 years versus an established quadrivalent HPV vaccine in women aged 15–26 years in India: a randomised, active-controlled, multicentre, phase 2/3 trial - The Lancet Oncology](https://www.thelancet.com)

⁸ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4528880/>



- The reported 1% serious side effects, not being specified, further adds to the ambiguity surrounding the vaccine's safety profile.
- Serious adverse events occurred in three (1%) girls and three (1%) boys in the SIIPL vaccine group, and five (1%) girls in the comparator vaccine group
- Lastly, the absence of long-term follow-up data raises concerns about the sustainability of the observed effects and potential unforeseen consequences over time.

These collective concerns underscore the need for a more rigorous and transparent evaluation of Cervavac's safety and efficacy.

Approvals and Recent Developments:

While Cervavac received approvals and recommendations, recent developments, such as the request for revised phase III trial protocols, highlight uncertainties about the vaccine's safety and efficacy⁹. The short-term nature of trials, lack of long-term follow-up data, and concerns over the study's design add to the scepticisms¹⁰.

Aggressive Marketing:

The aggressive marketing of HPV vaccines including those by celebrities on social media, inducing fear about HPV and cervical cancer creates an inaccurate impression of a 'Public Health Emergency'. The marketing of HPV vaccines without sufficient evidence of efficacy and safety of the vaccine, raises ethical concerns.

Financial Implications:

It is important to note that Cervical cancer mortality rate in India declined by 32% without any vaccination programme¹¹. It is clear that prevention is better than cure; the financial burden of mass vaccination without clear evidence of effectiveness, especially when other preventive measures are available, should be carefully evaluated.¹² We may spend a huge amount of taxpayer money on vaccines for all where only a minority may be at risk. A cost effectiveness study published in the NEJM in 2008 concluded that if the vaccine provided protection against HPV for only 10 years, then vaccinating preadolescent girls would only provide a "2% marginal improvement in the reduction in the risk of cervical cancer as compared with screening alone."¹³

Conclusion:

The current vaccines target only two oncogenic types: HPV-16 and HPV-18. Secondly, the relationship between infection at a young age and the development of cancer 20-40 years later is not known¹⁴. So how should a parent, physician, politician, or anyone else decide whether it is a good thing to give young girls the vaccine that partly prevents infection caused by a sexually transmitted disease that in a few cases will cause cancer 20-40 years from now?

In light of these concerns, we respectfully request that you consider the following steps:

⁹ [SII's Cervavac: The new DCGI approved vaccine without published clinical trial results – Biotech Express Magazine](#)

¹⁰ [SEC asks SII to submit revised phase III trial protocol for consideration of its cervical cancer vaccine Cervavac \(pharmabiz.com\)](#)

¹¹ <https://bmccancer.biomedcentral.com/articles/10.1186/s12885-022-09232-w>

¹² <https://medlarge.com/news/covid-19-updates/why-including-hpv-vaccine-in-national-program-is-waste-of-public-fund-explains-top-epidemiologist>

¹³ [Health and economic implications of HPV vaccination in the United States - PubMed \(nih.gov\)](#)

¹⁴ [Human papillomavirus \(HPV\) vaccine policy and evidence-based medicine: Are they at odds? \(mysu.org.uy\)](#)



1. The Government should review the decision to rollout / “encourage” the HPV vaccine in the mass immunisation programmes in the absence of sufficient long-term evidence of its effectiveness and complete and unbiased information, and without any prior public debate. The huge cost incurred in this mass immunisation even if the current price of the vaccine is reduced substantially should be seriously considered.
2. The Government should initiate comprehensive access to reproductive and sexual health programmes / services for adolescents, women and men including access to Pap screenings.
3. Instead of an expensive vaccination strategy, monitoring measures should be made available to detect cervical cancer at a very early stage. Treatment of all women with the diagnosis of cervical cancer is likely to cost the public healthcare system much less than buying the vaccine.¹⁵
4. Financial support from industry or from an international organisation should not be the criterion to introduce any vaccine in a pilot phase or in a universal immunisation programme.
5. All trials and studies to be immediately brought to a halt till, in an open forum, questions relating to the safety, efficacy and cost effectiveness of the planned intervention can be justified.
6. To place before the public:
 - All the documents pertaining to the agreement with vaccine manufacturers and all other bodies regarding the government’s plan to introduce the HPV vaccine. The list of all trials planned, proposed, approved and completed, the agencies involved, the donors involved and the proposed locations and all the results of the pilot phase trials as well as clinical trials.¹⁶
 - The estimated total cost, as per the government’s assessment, of purchase of the vaccine and its administration.

We appreciate your attention to this matter and trust that you will prioritize the health and safety of our citizens in all decision-making processes.

Thank you for your time and consideration.

Sincerely,

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¹⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5138175/>

¹⁶ <https://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2811%2960270-5/references>



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