MITALI SETT, Adv

Punjab & Haryana High Court

Ex-Legal Consultant, Revenue Department, Govt. of National Capital Territory of Delhi.

SP KIDWAI NAGAR EAST SD <110023 Counter No:2,26/09/2024,14:49 To:DHARAMENDRA,. PIN:110002, Indraprastha HD From:GAMBHIR AND JURISTS,. Wt:75gms Amt:29.50,Tax:4.50,Amt.Paid:30.00(Cash) <Track on www.indiapost.gov.in> <Dial 18002666868> <Wear Masks, Stay Safe>

ED594495709IN IVR: 6968594495709

New Delhi Office : F-50, South Mkt, East Kidwai Nagar, N.D-110023. Res. & Office: C-2/18, G.F, DLF Valley, Panchkula, Haryana - 134109

To,

Date: 25.09.2024

भारतीय

#### THE CHIEF SECRETARY OF DELHI

*Office at* : 3<sup>rd</sup> Level, Delhi Secretariat Indraprastha Extension, Delhi - 1100 02.

ON BEHALF OF CLIENT:

- 1. Dr. Sujata Mittal, MBBS, MS | New Delhi.
- 2. Dr.Nisheetha Dixit, MBBS, DIP, Gynae & Obst. Hyderabad
- 3. Smt. Nisha Koiri W/o. Sh. Ambar Koiri R/o. Mumbai
- 4. Smt.Sunita Koiri W/o. Sh. Vivek Koiri R/o. Mumbai.
- 5. Sh. Maheshwar Chowdhury S/o. Sh. Paramhans R/o. Bhojpur, Bihar
- 6. Sh. O.P. Sharma S/o. Sh. L.B. Sharma R/o. Bhojpur, Bihar

members of Awaken India Movement, Delhi Chapter.

#### **CEASE AND DESIST CUM CONTEMPT NOTICE IN RESPECT** SUBJECT • OF SUPREME COURT'S MANDATE ON INFORMED CONSENT FOR VACCINATION AND ALSO REG. PREVENTION OF **MISREPRESENTATION** 1 DECEITFUL ACTS BY WAY OF **INCOMPLETE FACTS ON HPV VACCINATION DRIVE ORGANIZED** BY THE STATE'S AGENCIES..

Sir / Madam,

I have been instructed by certain members of the Awaken India Movement (Said Social Organization) which notably includes very Senior Academicians, Noted Professors and respectable Doctors of eminence in their specialized fields, to serve upon this notice. That the above said Social Organization is a non-profit, non-religious, nonpolitical community of Indian Citizens who share a common understanding and responsibility towards the larger societal issues and primarily focusing on Health and Human Rights.

Their unanimous medical opinions on the roll-out of the HPV Vaccinations by the Govt. Agencies in coordination with Rotary Club & other social institutions is a major cause of concern which immediately require Long-term impact assessment and further exhaustive studies on the same. In this regard, your kind attention is drawn to the following:

(1) That the Hon'ble Supreme Court in its order dated **May 2<sup>nd</sup>**, **2022** in the landmark case titled as **'Jacob Puliyel vs. Union of India' W.P (C) No. 607 of 2021** has firmly upheld the Golden Rule of **'INFORMED CONSENT'** of Parents being absolutely mandatory prior to administration of any vaccinations in children. It has thus mandated :

- a. Authorities and Doctors administering the vaccines are duty bound to take 'INFORMED CONSENT' from the parents and as well as <u>advertise widely about the contents and adverse events of the</u> <u>vaccines</u>.
- b. That no one can ask the parents their reason for refusing consent for administering vaccines to their children
- (2) In this premise, it is brought to your urgent attention that the various programs being conducted under the aegis of the Ministry of Health and Family Welfare (MoFHW), State Education Boards and District Level Health Authorities who are organizing mass scale free Vaccination drives on 'HPV & Prevention of Cervical Cancer' among young girls, is grossly violative as stated in the case, Supra regarding Vaccination.

- (3) That it is pertinent to mention that several studies published worldwide by eminent Doctors, Gynecologists, Oncologists and Molecular Biologistss including Dr. Christian Fionna, Head of Department of Oncology in Vienna, have established that HPV or the Human Papilloma Virus is in itself not directly a causative factor of contracting Cervical Cancer among women at later stages of their lives. Various other co-factors which include smoking, alcohol and drug abuse, and STD's (Sexually Transmitted Diseases), unprotective sex with multiple partners and poor personal hygiene are major causative factors which may lead to Cervical Cancer among Women at later stages in their lives. To summarize the findings, it is still debatable worldwide whether HPV is the actual root cause of developing cervical cancer and even if HPV is a contributing factor, HPV or human papilloma virus has more than 200 sub-types, out of which only Sub-Type 16 HPV and Sub-Type 18 HPV have been identified as causes of cervix infection. HPV Sub-types 6 and Sub-Types 11 may only cause genital warts which can be treated dermatologically and are not a cause of concern. Hence, the necessity of HPV Vaccines for preventing Cervical Cancer is based upon the contingency which may or may not develop in Women at later stages of their life as the HPV Virus is still uncertain and requires further studies.
- (4) The **Universal Declaration on Bioethics and Human Rights, 2005** under Article 6 enumerates and mandates for informed consent as under :

"Any preventive, diagnostic and therapeutical medical intervention is only to be carried out with the **prior**, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate be expressed and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice." (5) The Hon'ble Supreme Court in the matter pertaining to MR vaccines has already propounded a <u>very significant concept of Large scale</u>, <u>understandable and lucid Advertisements (Master Haridaan Kumar vs.</u> <u>Union of India 2019 SCC Online Del 11929</u>) to be observed by State Agencies for proper dissemination of information relating the adverse <u>effects</u>. The relevant paragraphs are reproduced here:

"14. The Contention that indication of the side effects and contradictions in the advertisements would discourage parents or quardians from consenting to the MR campaign and therefore the same should be avoided, The entire object of issuing advertisements is to is unmerited. ensure that necessary information is available to all parents/guardians in order that they can take an informed decision. The Respondents are not only required to indicate the benefits of the MR Vaccine but also to indicate the side effects or contraindications so that the parents/ guardians can take an informed decision whether the Vaccine is to be administered to their wards/ children."

#### **"15.** In view of the above, it is directed as under..."

"...MR Vaccines will not be administered to those students whose Parents/ Guardians have declined to give their consent. The Said vaccination will be administered only to those students whose parents have given their consent either by returning the consent forms or by conforming to the same directly to the class teacher/ nodal teacher...".

"<u>Directorate of Family Welfare shall issue quarter page</u> <u>advertisements in various newspapers</u> as indicated by the Respondents namely, The Hindustan Times, The Times of India, The Hindu, The Pioneer, The Indian Express, Delhi Tribune, Mail Today, The Asian Age, Navbharat Times, Dainik Jagran, Punjab Kesari, Hindustan, Amar Ujala, Navodaya Times, Hamara Samaj, Prat ap, Daur-e-Jadeed, Jathedar, Jan Ekta. The Advertisements shall also indicate that the vaccination shall be administered with Auto Disable Syringes to the eligible children by Auxiliary Nurse Midwifery."

# <u>"The Advertisement shall also clearly indicate the side effects and contraindications as may be finalized by the Department of Preventive Medicine, All India Institute of Medical Sciences."</u>

(6) In the premise of the above stated judgments which act as the 'Law of the Land' and in conjunction with the Universal Declarations having International Sanctity, a Comprehensive note has been prepared by the complainants which immediately require a further in-depth analysis and scrutiny by the Government. A copy of this Note is appended herewith as 'Annexure-A' alongwith this Notice for your perusal.

Further, the life-long health and safety of every Girl Child must be kept paramount and <u>inorder to protect the individual Human Rights of every</u> <u>Girl Child who is the intended beneficiary of the HPV Vaccine, following</u> <u>demands / pre-requisites to be met for Vaccination ;</u>

#### **<u>"MANDATORY PRE-REQUISITES FOR VACCINATIONS</u></u>**

#### A) Wide publicity of list of all possible side-effects of vaccine

While the Government incurs heavy financial burden while implementation of free health schemes and in administration of Free Vacines Doses to the target beneficiaries (in this case Girl Child of age group 06-16 years for HPV Vaccine against prevention of Cervical Cancer) and Advertises its programs by different means both in offline and online modes, but it severely lacks in transparently and honestly disclosing the list of actual possible side-effects / Advserse Effects of Immunization (AEFI) which can be detrimental to the Vacinee in the future and is vitally necessary before taking a decision to get the Vaccine by any Individual.

In case of HPV Vaccines, globally various developed Nations including Japan, United States of America, France and Germany have published the list of possible side effects of HPV which include inter alia, Respiratory Ailments, Blood clotting, Fertility issues, Guillian Barre' Syndrome (GBS). <u>Such list of possible side -effects must be widely</u> **published by Government alongwith the actual advertisement** calling out for Vaccine Program/ Day of Event activity. This information must be disclosed in ordinary, plain and local language for easy comprehension of citizens.

### B) Complete & transparent disclosure of the actual ingredients used in the Vaccine

The Golden principle of 'Informed Consent' is cardinally rooted in the access to clear, transparent and honest information being made available to the Parents/Gaurdians (incase of Vaccines for Children) and to the Adult themselves before they can decide whether to take the Vaccine or not. Thus, it is imperative that prior to implementation of the Vaccination Drive, the actual list of the ingredients including the active, inactive components, carrier and all the components of the Vaccine are clearly mentioned and disclosed to the Public. For instance, the international HPV Vaccine Gardasil®9 (Human Papillomavirus 9-valent Vaccine, Recombinant) specifies the list of ingredients as :

- Proteins of HPV Types 6, 11, 16, 18, 31, 33, 45, 52 and 58
- Amorphous Aluminium Hydroxyphosphate Sulphate
- Yeast Protein
- Sodium Chloride
- Histidine
- Polysorbate 80
- Sodium Borate and Water

Any person who is allergic to any one of the above ingredients either taken individually or in a combination of one or more ingredients will thus be more susceptible to developing adverse reaction to Gardasil® 9 and the Vaccine Manufacturer themselves caution against such person from taking the Vaccine.

The list of Ingredients used in indigenously developed Cervavac Vaccine and anyother HPV Vaccine which is being administered to the girls aged 06-16 years must be disclosed and informed to their parents for assessment of specific allergies / adverse reaction development and the failure to do so shall be deemed violative of the Human Rights of the Vacinee.

## C) Actual contents of Patient Information Booklet must be disclosed before taking informed consent.

Patient Information Booklets are statutorily required to be inserted in every carton of Vaccine Serum, by the Vaccine Manufacturers which must clearly state the list of ingredients, uses and advantages of the Vaccine, limitations of the Vaccine and the possible list of side effects of the same. This Patient Information Booklet should be printed in <u>atleast two languages</u>, official language like Hindi or English and in <u>one local vernacular language</u> for the comprehension of every Parent/ Guardian before deciding to get their children vaccinated.

#### D) Complete health analysis of every intended vacinee / Minor Child in case of HPV Vaccination.

The health parameters of every Girl child including her vitals, any past medical history or ailments like asthma, respiratory disorders, Blood infections and all other medical conditions which may affect or result in the AEFI must be assessed prior to actual vaccination.

#### E) Risk versus Benefits comparison for every intended Vacinee

Global HPV Vaccine Manufacturers have clearly indicated in their respective Patient Information Booklets, that **before administering the Vaccine, every Health Care Professional / Doctor must prepare a** 

### <u>compulsory Health Report of the Risks versus Benefits of the Vaccine</u> <u>and whether or not a Vacinee ( recipient of the Vaccine dose) is</u> <u>eligible or medically fit to receive the same.</u>

\_The State Government must ensure that this Risk Assessment is done by competent Medical Doctors to weigh in and judge whether a Girl Child will eventually benefit from the HPV Vacine or the administration of the same may result in serious irreparable injury, loss of life or be detrimental to her health in any manner in the future.

7) In view of the above highlighted issues, the <u>Mass Scale Vaccination camps</u> that are being organised for young girls under your State's administration for said 'prevention of Cervical Cancer through HPV' is thus grossly illegal and unlawful as the essential pre-requisites are not being performed resulting in the violation of Human Rights of the intended Vacinee.

THUS, YOU ARE HEREBY REQUESTED TO IMMEDIATELY ORDER FOR THE CEASE AND DESIST OF ANY ACTIVITIES, PROMOTIONS, SCHEMES, PROGRAMS, CAMPAIGNS RELATED TO THE ONGOING "<u>HUMAN</u> <u>PAPILLOMA VIRUS (HPV) VACCINATION FOR SO CALLED PREVENTION</u> <u>OF THE CERVICAL CANCER</u>" AMONG YOUNG GIRLS, WHICH ARE BEING CONDUCTED UNDER YOUR ADMINISTRATION WITHOUT THE DUE COMPLIANCE OF THE LAW OF THE LAND AND TO KEEP THE SAME IN ABEYANCE PENDING THE ACTUAL DETERMINATION OF THIS ISSUE, FAILING WHICH ANY ADVERSE EVENTS AS MAY BE REPORTED BY ANY VACINEE, OR ANY LOSS OF INNOCENT LIVES DUE TO THE SERIOUS REACTIONS OF THE HPV VACCINES, SHALL BE ENTIRELY AT YOUR RISK AND YOU SHALL BE LIABLE FOR THE SAME, WITHOUT PREJUDICE TO THE OTHER AVAILABLE LEGAL REMEDIES FOR THE SAME.

Regards.

Mitali Sett, Adv. Enclosure : 1. Note on HPV signed by Panel of 50 + Doctors



### An Initiative By: Awaken India Movement- AlM



mail2aim@protonmail.ch awakenindiamovement.com

Annexure 'A'

#### Grievance Registration Number : DHLTH/E/2024/0004106

Shri Mansukh Mandaviya, Union Minister, Ministry of Health and Family Welfare, Government of India, Nirman Bhawan, New Delhi – 110108

#### 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.

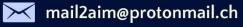
#### Lack of Evidence on causes and prevention of Cervical Cancer:

Clinical trials have failed to provide conclusive evidence that the HPV vaccine effectively prevents cervical cancer<sup>1</sup>. 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

<sup>&</sup>lt;sup>1</sup> 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 agestandardized 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 cancer<sup>2</sup>. Early sexual contact, alcohol, smoking etc. are risk factors for cervical cancer.<sup>3</sup>

#### **Serious Adverse Reactions:**

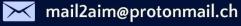
The HPV vaccine has been associated with serious adverse events, including autoimmune disorders, multiple sclerosis, Guillain-Barré syndrome, paralysis, chronic fatigue syndrome, and even death. Malfunctions of the autonomic nervous system, cognitive dysfunctions, gait disturbances, menstrual problems and ovarian failure have all been reported following HPV vaccination as well<sup>4</sup>.

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:



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

<sup>&</sup>lt;sup>3</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4404964/

<sup>&</sup>lt;sup>4</sup> <u>Microsoft Word - 1.26.16 - New Concerns about the HPV vaccine.docx (acpeds.org)</u>

#### 3/6

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 illnesses<sup>5</sup>. 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 72<sup>nd</sup> 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 screening<sup>6</sup>. 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:

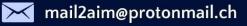
- Vaccination will not result in protection in all vaccine recipients.
- It is only for prophylactic use and has no effect on active infections.
- CERVAVAC® has not been demonstrated to protect against diseases due to HPV types not contained in the vaccine
- The vaccine is not an alternative to routine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

#### **Concerns over Cervavac trials**

The concerns over the Cervavac trials are multi-faceted, raising significant doubts about the comprehensiveness and reliability of the study<sup>7</sup>.

- 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 fertility<sup>8</sup>, a critical aspect that should be thoroughly examined.





<sup>&</sup>lt;sup>5</sup> Trials and tribulations: an expose of the HPV vaccine trials by the 72nd Parliamentary Standing Committee Report – Sama (samawomenshealth.in)

qHPV - SmPC 2022.pdf (cdsco.gov.in)

 <sup>&</sup>lt;sup>7</sup> 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
<u>8</u> <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4528880/</u>

- 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 efficacy<sup>9</sup>. The short-term nature of trials, lack of long-term follow-up data, and concerns over the study's design add to the scepticisms<sup>10</sup>.

#### **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 programme<sup>11</sup>. 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.<sup>12</sup> 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 known<sup>14</sup>. 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:



<sup>&</sup>lt;sup>9</sup> SII's Cervevac: The new DCGI approved vaccine without published clinical trial results – Biotech Express Magazine

<sup>&</sup>lt;sup>10</sup> SEC asks SII to submit revised phase III trial protocol for consideration of its cervical cancer vaccine Cervavac (pharmabiz.com) <sup>11</sup> https://bmccancer.biomedcentral.com/articles/10.1186/s12885-022-09232-w

<sup>&</sup>lt;sup>12</sup> https://medlarge.com/news/covid-19-updates/why-including-hpv-vaccine-in-national-program-is-waste-of-public-fund-explains-topepidemiologist

<sup>&</sup>lt;sup>13</sup> Health and economic implications of HPV vaccination in the United States - PubMed (nih.gov)

<sup>&</sup>lt;sup>14</sup> 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.<sup>15</sup>
- 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.<sup>16</sup>
  - 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,

#### List of Signatory Doctors.

- 1. Dr. Amitav Banerjee, MD, Pune
- 2. Dr. Jacob M Puliyel, MD, MRCP, MPhil, Paediatrician, New Delhi
- 3. Dr. Sujata Mittal, MBBS, MS, New Delhi
- 4. Dr. Nisheetha Dixit, MBBS, Dip Gyne & Obs, Hyderabad
- 5. Dr. Lalitkumar Anande, MBBS, PG Diploma in Clinical Research, Mumbai
- 6. Dr. Megha Consul, MD Paediatrics, Neonatologist, Gurgaon
- 7. Dr. Maya Valecha, MD, DGO, Vadodara
- 8. Dr. Banu Prakash, Neurosurgeon, Bangalore
- 9. Dr. Veena Raghava, MBBS, DA, Bangalore
- 10. Dr. Vijaya Raghava, MBBS, Bangalore



<sup>&</sup>lt;sup>15</sup> <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5138175/</u>

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

- 11. Dr. Rajendra Tiwari, DNB, DOG, FCPS, DGO(CPS), DFP, Dahanu
- 12. Dr. Ashish Kale, MBBS, DGO, DFP, Mumbai
- 13. Dr. Geraldine Sanjay, B.Sc, MBBS, DFM, MD, Bangalore
- 14. Dr. Amol Javdekar, MBBS, MD (Pathology), Pune
- 15. Dr. Kuldeep Kumar, MBBS MS(General Surgery), Haridwar
- 16. Dr. Chandrasekhar Thodupunuri, MBBS, PGDCC, Hyderabad
- 17. Dr. Praveen Saxena, Radiologist, MBBS, DMRD, Hyderabad
- 18. Dr. Mamta Singla, MBBS, MS Surgery, Haryana
- 19. Dr. Manisha Gandhewar, MBBS, MD, DGO, Mumbai
- 20. Dr. Tarun Kothari, MBBS, MD, New Delhi
- 21. Dr. Gautam Das, MBBS, Kolkata
- 22. Dr. Gayatri Ajit Swamy, MBBS DA, Pune
- 23. Dr. Sayed Tahir, MBBS, MD, Bangalore
- 24. Dr. Jacob Vadakkanchery, Naturopath
- 25. Dr. Biswaroop Roy Chowdhury, Ph.D (Diabetes), Faridabad
- 26. Dr. N K Sharma, ND, Naturopath, Delhi
- 27. Dr. Arun Sharma, N.D., International Institute of Mahayoga & Natural Hygiene
- 28. Dr. Madhuri Patil, BAMS(Mumbai) MD (Ayurveda Samhita and Siddhant)
- 29. Dr. Abhay Chheda, BHMS, CCAH, FCAH, Mumbai
- 30. Dr. Firuzi Mehta, B.H.M.S. (Bom.), H.M.D. (Lon.), IACH DIHom (Gr.), Mumbai
- 31. Dr. Remya Krishnan, MD PhD (Ayurveda), Kannur
- 32. Dr. Ambati Surendra Raju, DHMS, Hyderabad
- 33. Dr. Anil Kumar T P, MD Homeo, Thiruvananthapuram
- 34. Dr. Khadar Valli, PhD, IISC, Mysuru
- 35. Dr. Shaji Varghese Kudiyat, BHMS, MD(Hom), Kothamangalam
- 36. Dr. Avneet Kaur Matharu, BHMS, PGDEMS, Mumbai
- 37. Dr. Babu Joseph, Naturopathy, Pune
- 38. Dr. G Prema MD (Hom), PhD, Tamil Nadu
- 39. Dr. Gayatri Panditrao, Homeopathic Physician, BHMS, PGDEMS, Pune
- 40. Dr. Heta Prasad, MD Homeo, Mumbai
- 41. Dr. Ketaki Kulkarni, BHMS, Mumbai
- 42. Dr. Madhura Pade, BHMS, CCAH, PGCDE, Nashik
- 43. Dr. Monika Parekh, BHMS, Virar
- 44. Dr. Neeta Bhargav, BHMS, Homeopathic physician, New Delhi
- 45. Dr. Omkar Pradeep Mhashelkar, BHMS, MD Homeo, Mumbai
- 46. Dr. Pallavi Chaturvedi, BHMS, Mumbai
- 47. Dr. Rashmi Menon, BHMS, ChT, Mumbai
- 48. Dr. Shorav Bhatnagar, Interventional Radiologist, Faridabad
- 49. Dr. Sudhir Jagtap, MD, Pune
- 50. Dr. Susan Raj, BSc Nurse, MSW (M&P), Doctorate-Humanities, Chhattisgarh
- 51. Dr. Swathi Sharmaa, BHMS, Bangalore
- 52. Dr. Urvi Savla, MD(Homeopathy), F.C.A.H., Vasai
- 53. Dr. V. Pugazhendhi, MBBS, Kalpakkam
- 54. Dr. Vimal Soni, Speciality Homeopathy, Beawar
- 55. Dr. Vishakha Moghe, B.A.M.S, Goa
- 56. Dr Radhika Wagle, PHd. Biochemistry, Pune