1. The government has plans to introduce the Human Papilloma Virus (HPV) vaccine into the immunisation programme. The National Technology Advisory Group on Immunisation is reportedly tasked with deciding the date. The HPV vaccine is the latest in a string of new vaccines being pushed for the government programme despite many questions being asked about their safety, efficacy and public health priority. Are decisions being made in the interest of the public good? Or do they benefit private interests like the vaccine manufacturers? How do they shape the government’s responsibilities? Will such magic bullets make a difference? Has the government acted correctly?
2. Diverse activists have come out against the introduction of the HPV vaccine into the government programme.
3. Even those who believe the vaccine’s safety is not an issue, and that even a 70% efficacy is good enough at the public health level, the vaccine’s price should rule out its use. The government will most probably negotiate with the manufacturer to bring down the price a bit, and then work out a deal with the BMGF controlled Global Alliance for Vaccines and Immunisation (GAVI) for co-finance. But
4. This would follow the ingress of a number of new vaccines – against rotavirus infection, http://www.deccanherald.com/content/496411/3-vaccines-added-immunisation-programme.html
5. Public needs to call for such plans to be made public and public opinion sought.
6. Ca cx is a serious problem in India, affecting … and killing … women every year. Most of these women are poor, and died because they did not have access to basic screening and treatment services. The cancer was detected late, or they could not get treatment. Provision of health services have been largely neglected by governments which choose to focus, instead, on “magic bullets” like vaccines, an approach that favours industry or, rather, a nexus between government and industry. Thus the Bill and Melinda Gates Foundation’s philanthrocapitalism,
7. HPV is a major cause of ca cx. The two vaccines, by Merck and GSK are said to present some **70%** of cervical cancers.
8. Issues: safety, efficacy, cost, priority as a public health measure, other options.

   About relative safety of HPV vaccine, it is to be noted that lacs of women in  developed countries have received this vaccine and there has not been so many dangerous side-effects on an alarming scale. But in India, HPV vaccine is being considered for a v  large scale use in the National Programme. The incidence and seriousness of  side effects of HPV vaccine have to be compared with those of the established vaccines in the National Programme. For example, with DTP; while taking note of the fact that DTP has about a dozen documented side-effects including some serious ones. Overall, in India, unless there are well done, sufficiently large studies on HPV vaccine to ascertain their relative safety for use in the National programme in Indian conditions, there is  no question of declaring it as safe for inclusion in the  National programme.

We, the concerned representatives of public health networks, women’s groups, health researchers, health and women’s rights activists and individuals are writing to you to convey our shock and concern over the Union Government’s plan (reported in *Asian Age* <http://www.asianage.com/india/government-plans-reintroduce-hpv-vaccine-308>) to introduce the human papillomavirus (HPV)vaccine in the Universal Immunization Programme (UIP). According to the newspaper report, the Government has asked the National Technical Advisory Group on Immunisation (NTAGI) to conduct a feasibility study in the next three months on the vaccine so that it can be introduced in the country. We are extremely concerned about the long-term safety and efficacy of the HPVvaccines—Gardasil and Cervarix—and strongly feel that it would lead to serious adverse effects for its recipients. The Supreme Court is hearing the writ petitions that have raised important questions regarding the vaccine's safety and efficacy as well as its relevance and priority as a public health measure in India.

At the outset we would like to bring to your notice that the HPV will by itself not reduce the rate of cervical cancer in India. It is well documented that HPVinfection is a necessary cause of cervical cancer; however, since every woman with HPV infection does not develop cervical cancer, it is not necessarily a sufficient cause. Other factors are necessary for progression from cervical HPVinfection to cancer. Long-term use of hormonal contraceptives, high parity (number of times given birth), early initiation of sexual activity, multiple sex partners, tobacco smoking and co-infection with HIV have been identified as established factors; co-infection with Chlamydia trachomatis and herpes simplex virus type-2, immuno-suppression, low socioeconomic status, poor hygiene and diet low in antioxidants are other probable factors influencing the progression of cervical cancer. Genetic and immunological host factors and viral factors such as variants of type, viral load and viral integration are likely to be important, though they have not yet been clearly evaluated.

Further, there is a lot unknown about HPV vaccines even today, including whether a repeat dose is required and how long the vaccine might protect fromHPV infection. There is no conclusive evidence which suggests that the vaccine will protect girls from acquiring HPV and developing cervical cancer later in their life. These vaccines have not been in use for long enough to know the level of protection they will offer to young women when they are actually exposed to the risk of HPV infection.

The impact of the vaccines on the health of adolescents is also not known. For instance, individual case reports of CRPS (Complex Regional Pain Syndrome) and POTs (Postural Orthostatic Tachycardia Syndrome) have been reported following HPV vaccinations from several countries including Australia, Germany, Japan, the US and Denmark. The Danish Health and Medicines Authority has drawn the attention of the European Medicines Agency (EMA) towards the vaccine’s safety and efficacy and the EMA is currently conducting a review of the vaccine’s safety profile.

(<http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2015/07/WC500189481.pdf>)

There is little evidence of the safety and efficacy of the HPV vaccine in the Indian context. These vaccines were hurriedly licensed here, on the basis of grossly insufficient research; the Cervarix trial was restricted to women and Gardasil was introduced after a trial with only 110 girls and no adult women.

Government committees have criticised both scientific and ethical aspects of the vaccines’ introduction in India. The 41st Report of the Parliamentary Standing Committee had called for an enquiry into the licensing of the products. However, no enquiry was conducted. The 72nd Parliamentary Standing Committee found gross under-reporting of adverse events in the only large scale “demonstration” study of the two vaccines, on girls between 9 and 16, carried out in Gujarat and Telangana by the US-based NGO Programme for Appropriate Technology in Health (PATH) in collaboration with the Indian Council of Medical Research (ICMR).

A number of girls experienced side effects and at least 7 died post vaccination. The Parliamentary Standing Committee concluded that the girls’ deaths were not properly investigated and that they were instead summarily dismissed as being unrelated to the vaccine. The Committee also concluded that PATH’s demonstration study violated the rights of the vaccinated girls and called for an enquiry by the National Human Rights Commission (NHRC) and the National Commission for the Protection of Child Rights (NCPCR).

Further, money and resources that would be spent on this vaccine should be spent to strengthen health services including screening for cervical cancer. These include large-scale awareness programmes (including through sex education for girls) on HPV, cervical cancer, methods of preventing transmission of sexually transmitted infections, and the need for screening. This will have a far greater impact in reducing the incidence of and mortality from cervical cancer. Indeed, the Planning Commission’s working group on Non-Communicable Diseases (NCD) for the 12th Five Year Plan recommended that “at this juncture emphasis on availability of HPV vaccine at district level may not be required as simple advice on personal hygiene and early symptoms of Cervix Cancer and training of Health worker in VIA techniques will help in prevention & early detection of cervix cancers”. (Proposal for the 12th five year plan, working group on NCDs, Planning Commission, GoI, pg 100).

Finally, you are well aware that the Supreme Court is still waiting to hear from the DCGI and the ICMR on its order of 12th August 2014, calling on them to produce the files relating to the licensing and collaboration with PATH before the court in the matter of Writ Petition (civil) 558/2012 Kalpana Mehta and others vs Union of India and others and Writ Petition (civil) No.921/2013 Sama and others vs UoI and others. It is unacceptable to ask NTAGI to look into the feasibility of the vaccine when the Health Ministry has failed to comply with the order with respect to licensing that deal with safety and effectiveness of these vaccines.

We sincerely urge you to call an immediate halt to any attempts to introduce the HPV vaccines in the Universal Immunization Programme in the larger interest of the health and well-being of the adolescent girls and women of this country.

Signed by: