

Press Release
April 7th, 2010 – World Health Day
Unethical Medical Intervention to prevent HPV infection by the government in collusion with drug company and foreign NGO renders poor tribal girls dead and debilitated

Protests, representations and extensive coverage in the media against PATH-ICMR project being carried out in AP and Gujarat seem to have fallen on deaf ears and the government has gone ahead with a vaccination programme with Gardasil (HPV vaccine manufactured by Merck) leading to four deaths and 120 girls suffering from debilitating new illnesses like epilepsy, headaches, stomach disorders and early menarche.

The girls, 10-14 years old, belonging to poor families, were enrolled in a study being carried out jointly by PATH (an International NGO), Indian Council of Medical Research and the respective state governments funded by Bill and Melinda Gates Foundation. The objective of this two year study is to look into acceptability and service delivery issues of Gardasil, marketed in India by MSD Pharmaceuticals Pvt. Ltd, being misleadingly promoted as a preventive for cervical cancer.

The literature circulated in the project makes outright false statements about its safety, efficacy and duration of effectiveness. The girls and their parents have been told through the project documents that the vaccine will give life long immunity, has no side effects other than minor ones like fever and rash and will not affect future fertility of the young girls.

When deaths started getting reported local groups in Andhra Pradesh were alarmed by and carried out a fact finding to discover that no consent was taken from parents and the girls and their families have been left uncared for. Post mortem reports were also not easily accessible, and in cases of death cover up was the general dictum.

We question:

1. Why are poor girls and their families being actively misled? Who is liable for the debilitating effects of the vaccine and who will medically look after these girls and pay compensation for the damages suffered by these people?
2. How has the government embarked on this study of giving three injections to the girls when it is also planning a massive multi-centric dose determination study to see if two doses will suffice?
3. How has the Drugs Controller General granted approval to the vaccine without proper research in India? For a drug to be administered to children, it has to go through stages of clinical trial, including Phase 3 adult clinical trials. So far with Gardasil only one trial has been carried out with just a small sample of 110 girls which has followed them up for just one month after the completion of vaccination and that too only to look at the immune response post vaccination. The vaccine has also been approved for adult women till 27 years of age without doing any trials with them at all.
4. Why are these studies being carried out when at various times the concerned government officials have gone on record to say that it is not feasible for the vaccine to be introduced in the Indian Public Health system given its costs? Is

it not then using these poor girls as guinea pigs for a vaccine which can be used only in the private market by well to do families? Why is a two year study being carried out with no future guarantee even for the subjects of this study to keep them protected with boosters when they actually get married by when the effect of this vaccination will wear off? The effect of the vaccine seems to wear off after 4-5 years, and will require periodic booster injections to retain claimed effectiveness.

The path of licensing of the vaccine in India raises many serious questions as time and again scientific logic and the ethical guidelines have been violated at each step. Our law clearly states that no trials of drugs can be conducted among children before trials are conducted on adults. While the other HPV vaccine, Cervarix, made by GlaxoSmithKline has also been licensed in India it has been approved for use for children without any trials among them at all. It should be remembered that last year the two drug companies had engaged in massive advertisement of these vaccines in the media and are continuing with giving incentives to doctors and holding promotional camps in schools among the paying segment of the market.

All this is being done for products which have no proven value. Even the license given by US FDA has asked Merck to actually study whether there is a reduction in the incidence of cervical cancer due to vaccination.

Even as their effectiveness and usefulness remains unproven information on the adverse effects of these vaccines are pouring in from all quarters. The tally in US alone crossed the mark of 17000 adverse effects (as reported under the voluntary adverse effects reporting system); and even the US FDA gave a hearing to health advocates to present the case against the vaccines on March 12, 2010. The adverse effects include heart, immune, blood clotting, respiratory, nervous, digestive and musculoskeletal systems and occur with far greater frequency than those observed with any other vaccines. Many experts and established medical journals have already termed it the biggest public health experiment.

In the public health system of India this vaccination will prove to be an expensive and hazardous exercise. These vaccines at best protect against two sub types among 15 which are associated with cervical cancer and hence ideally women will have to undergo pap smear tests for an effective cancer control strategy along with various hygiene and nutrition related strategies. Unfortunately, there is no investment in screening which can help the adult population today.

We demand:

1. Complete suspension of all studies and trials with Gardasil and Cervarix and suspension of their licence for marketing in India till such time that a public enquiry is held on their licensing in violation to the India law.
2. Proper enquiry in the deaths in Khammam that have been dubbed as suicides. Unless it becomes clear that the vaccine has no impact on the mental health of girls the project authorities cannot be absolved of the blame.
3. Each vaccinated girl be examined by independent authority to assess the range and incidence of side effects. While this will provide the much needed information about vaccine safety it will also detail the care that these girls

require and the compensation they and their families deserve for having been actively misled.

4. Proper long term follow up of the vaccinated girls till they get married and have children and booster doses at the right time free of cost, with full informed consent for those girls who wish to continue vaccine protection.

Unless the government details a plan for cervical cancer control, with full compliment of boosters, screening and treatment this project is sheer experimentation with innocent, vulnerable and poor people of the society who can not afford this expensive vaccine. According to us the government is constitutionally bound to take care of the life of all citizens and not subject them to new medical problems at the behest of foreign NGOs.

Sama

All India Democratic Women's Association

Saheli

All India People's Science Network

Jan Swasthya Abhiyan