

**Ministry of Health & Family Welfare, Drugs Controller, ICMR,
GlaxoSmithKline, MSD Pharmaceuticals, PATH representatives, and Child Rights
Commissioner invited to public meeting where...**

**WOMEN'S ORGANISATIONS OPPOSE HPV VACCINES
'AGAINST CERVICAL CANCER'**

In a public meeting in New Delhi on 28 Dec 2009, women's groups Sama Resource Group for Women and Health and Saheli Women's Resource Centre, raised serious objections to the trials, study and marketing of HPV (human papillomavirus) vaccines claiming to protect young girls from cervical cancer in India. They condemned the blatant and irresponsible promotion of Gardasil and Cervarix, marketed by MSD Pharmaceuticals and Glaxo SmithKline (GSK) respectively in India for several reasons:

- The large number of reported adverse reactions to the vaccines, their un-established safety, serious long term side effects, astronomical costs and the fact that vaccine requires a robust screening system for cancer in order to benefit anyone.
- Ethical and procedural violations in trials and studies conducted and proposed in India
- Unacceptable public health implications
- Illegal and alarmist promotion and advertising
- Silence and inaction of part of government officials

These vaccines have been promoted heavily in U.S.A and U.K. with disastrous consequences, leaving a number of girls chronically ill with serious problems including the development of autoimmune disorders, loss of sensation and mobility and unfortunately, the death of nearly fifty young healthy girls. This has created such a strong consumer movement that within two years of introduction in the market, the sales of the Merck (the parent company of MSD Pharmaceuticals) have fallen by 30% after bringing in billion of dollars in sales in its first two years.

**Not a vaccine to 'prevent' cervical cancer;
only a vaccine against 2 among hundred HPV types**

Contrary to the propaganda being created around both the vaccines through advertising, promotion and lobbying, both Gardasil and Cervarix do NOT prevent cervical cancer; they merely act against 2 types of virus associated with cervical cancer. ***So what is the logic of subjecting young girls to such vaccines for an illness which a very few of them may acquire some thirty years later, due to persistent presence of HPV subtype 16 & 18.***

Problems and shortcomings of HPV vaccines

Despite having being 'studied on' and marketed to millions of healthy girls and women the world over, ***here is what neither Merck nor GSK know about the vaccines they are promoting:***

- The manufacturers ***do not know the minimum effective level of anti-bodies for the vaccine to be effective.*** A WHO funded trial is slated to study if 2 doses of the vaccine will suffice instead of the presently used 3 dose regimen.
- They ***do not know how long the effectiveness may last.*** There is firm data only for a period of 4-5 years, but cancer takes 10-20 years to develop.

- Leave alone benefiting women, ***Gardasil can worsen the chances of getting cancer by 144%.in those who were already infected with the HPV subtypes 16 and 18 when vaccinated.***
- ***30% of cancer causing virus strains are not covered by these vaccines.***
- The ***vaccines have not been studied*** in respect of their ability to cause cancer or mutagenicity.
- ***Effect on fertility, outcome of pregnancy and effect on breast milk have not been studied,*** yet they are being administered to young girls whose bodies have yet to mature.
- ***Post marketing surveillance shows*** that side effects thrown up in the US are very alarming in that they point to auto-immune diseases like lupus, arthritis etc., blood system disorders like clotting, seizures and other nervous system disorders like Guillian Barre syndrome and ALS. Depression and behavioural disorders have also been reported
- ***Above all, a number of girls have died.***

Unethical promotion of HPV vaccines

The overt promotion of these drugs is being carried out by the two drug companies to market their products in the paying segment. ***GlaxoSmithKline calls it a cancer prevention vaccine and lists no side effects but advises mothers to rush to the paediatricians*** (indicative of reaching out to girls under 12 years of age). This is objectionable because the company has not even carried out trials in India with this age group. The package insert for Gardasil marketed by Merck fails to mention the age at which the shots are to be given and has conducted trials in India with a mere 110 girls!

The Drugs Controller of India has taken exception to the advertising by Glaxo Smithkline, ***but the Merck vaccine*** has not only been left alone but is being allowed to be used in studies in rural, tribal areas of AP and Gujarat where ***researchers are claiming that the effect will last a life time (no research so far suggests it), there are no side effects except for mild reaction at the injection site (denying information in the company package insert) and the vaccine will not affect fertility or the chances of having a healthy baby (which is false as the drug has caused these problems in trials done so far).***

Faulty programme vision

At present ***a large study is being conducted by PATH , funded by the Bill and Melinda Gates Foundation in A.P. and Gujarat on 16,000+ girls, 10-14 yrs,*** to design effective and appropriate HPV vaccine delivery strategies, a communications and advocacy strategy.

Misinformation is not the only weakness of this study. Gardasil at present is being supplied for free but there is no commitment for keeping the subjects protected in the event they need booster doses. It is also worth noting that in the entire district of Khammam there is no screening facility available.

Violation of child rights

The MSD trials in India violate ICMR ethical guidelines that categorically state that children cannot be involved in trials unless the drug has been tested on adults. Merck did a trial on girls, with Gardasil in India, even before their trial with adults!

Also, the study in Khammam on 16,000 girls is tantamount to both ‘neglect’ and ‘physical abuse’ by the agencies, according to WHO guidelines on child abuse.

Disregard for the Welfare of girls

All in all, there is little logic in the way that this vaccine is being pushed by the licensing authorities, researchers and the governments without adequate testing and by hyping the problem of cervical cancer out of context. Since there is no plan to keep even trial subjects under protection we can safely conclude that they are just being used as guinea pigs. At best the data will come in handy to promote the vaccine in the third world for which these girls are bearing the cost – one girl has died in the course of trials already. There is no system to investigate deaths or compensate people for damages or taking punitive action against irresponsible researchers.

The money and clout of Merck and GlaxoSmithKline, has succeeded in gaining fast track clearances for these vaccines in several countries, and despite the backlash, they are all geared up to expand sales in the less developed world without any regard to the ground realities.

The story of HPV vaccines in India is one of blatant collusion of multinational corporations and business interests, international NGOs and government agencies. However, the State bears the final responsibility for the situation, and the State must act in the interests of the health of the women and children of India. Hence we demand:

- Immediate stoppage of all HPV vaccine studies
- Follow up of study subjects be conducted and made public
- Public clarification/apology from GlaxoSmithKline for the alarm created by its advertising blitz
- Withdrawal of all promotional activity by MSD pharmaceuticals
- Augmentation of screening facilities, especially in areas where the promotion of these vaccines has already occurred
- Awareness creation IEC programmes on RTI, STD, and cancers, including cervical cancer, with a focus on screening as the best course of action
- Fixing of liability on government officials/institutions with respect to ethical, legal, medical violations in the case of HPV vaccines
- Punitive action against all erring parties
- Enforcement of mandatory registration of all clinical trials
- Re-think on matters of public policy: per capita expenditure on serious illnesses must correspond to levels of morbidity/mortality
- The UPA govt must fulfill its election promise of increasing the health budget to 3% of GDP

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