सत्यमेव जयते

भारत सरकार
GOVERNMENT OF INDIA
राष्ट्रीय बालक अधिकार संरक्षण आयोग
NATIONAL COMMISSION FOR PROTECTION OF CHILD RIGHTS
नई दिल्ली -110 001
NEW DELHI - 110 001

AP-13015/10273/09-Comp/1657

Dated: 12/4/2010

To

Ms Nalini Bhanot,,
Saheli Women's resource Center,
Above Unit 105-108,
Defence Colony Flyover Market,
New Delhi 110024
Email:- SeheliWomen@gmail.com

Sub: Violation of Child Rights by ICMR and PATH international with respect to study of vaccination with Gardasil-Communicating a report-Reg.

Madam,

Please refer your petition sent through e-mail dated 18.11.2009 on the subject cited above. The matter was referred to the Principal Secretary, Department of Women Development, govt. of A.P by this Commission.

The Commissioner of Family Welfare & E.O. Principal Secretary to Govt, HM & Women Department, Govt of AP vide their letter dated 19.2.2010 has sent the reply, copy of which is enclosed for your information.

A report published in "The Hindu" dated 8/4/2010 is also enclosed for your information.

Yours faithfully

(Lov Verma)
Member Secretary

ENQUIRY REPORT

The attached letter from Saheli Women's Resource Centre to the Chairperson, National Commission for Child's Rights is unfortunately based on misperceptions and misinformation about the Post-licensure Observational Study of HPV vaccination in Khammam District, Andhra Pradesh.

Indian Council of Medical Research (ICMR), State Government of Gujarat and Andhra Pradesh in collaboration with a nonprofit organization PATH is implementing two operational research studies related to cancer of the cervix prevention in India (they are not clinical trials). The objectives are to generate critical data and experience for evidence-based decision making about public sector immunization programs as part of a broader cancer-of-the-cervix prevention and control strategy. The results of the demonstration project will be examined by a National Technical Advisory Group, of India (NTAGI) of the Government to advise the Hon'ble Minister of Health on further courses of action.

Please find our responses for the issues raised in the letter dated 19/11/1009 from Nalini Bhanot

No Phase III trial has been undertaken with this age group as mandated by the Drugs and Cosmetics Act

The statement is irrelevant as the ICMR-PATH research is not bio-medical research looking into the effectiveness or safety of the vaccines. This is not a clinical trial. No bio-medical outcomes are being researched, no blood or other samples are being drawn and no therapies are being tested. Clinical trials of the vaccines were completed long ago and both of them vaccines were licensed for use in India prior to inception of the ICMR-PATH project. Both vaccines are available in the private market throughout the country. These are not experimental products; they are approved, commercial products. The vaccines have been approved by the Drug Controller General of India (DCGI), US Food and Drug Administration (FDA), European Medicines Agency (EMEA) and other national regulatory bodies and pre-qualified by World Health Organisation (WHO) for purchase by United Nations Children's Fund (UNICEF).

This is a dose determination trial

• PATH-ICMR Post-licensure Observational Study of HPV vaccination in Khammam District, Andhra Pradesh is not a clinical trial. The objectives are to generate critical data and experience for evidence-based decision making about whether and how to introduce HPV vaccines into public sector immunization programs as part of a broader cancer-of-the-cervix prevention and control strategy. -

The vaccine is effective for a limited period

When the vaccines first were marketed internationally, the companies only had five years of data from clinical trials showing that the vaccines worked. So that "5 year" number was publicized at that time. However, as time goes by, the data accumulate. Now results from several international, randomized controlled studies with follow up of nearly eight years have shown that both vaccines induce high levels of antibodies against

the vaccine specific HPV types and the antibody levels were tenfold higher than following natural infection with HPV. The antibody levels correlates with vaccine efficacy and the current evidence does not indicate a reduced performance at eight years or indicate a need for booster doses.

Cost concerns

The letter also focuses on the cost of the vaccine in the private market and the cost-effectiveness of HPV vaccination. Again, no one would ever suggest that a Rs 3000/dose vaccine be introduced in the public sector in India. Once prices reduce substantially, however – either due to competition, local production or subsidization by organizations like the GAVI Alliance – the governments will be able to assess the cost-effectiveness of an affordable vaccine, and then decide whether to introduce the product or not. The demonstration project will generate important information about developing country demand for HPV vaccine, which will help manufacturers better assess their market opportunities and, we believe, lead them to better (lower) pricing decisions than they would otherwise make. India has similar experinace on cost reduction dynamics for newer and underutilized vaccines when introduced in public health system.

The study violates the guidelines for biomedical research of ICMR which states children should not be tested upon unless they stand to gain directly from the research

As stressed upon earlier PATH-ICMR's Post-licensure Observational Study of HPV vaccination in Khammam District, Andhra Pradesh is not a clinical trial. The HPV vaccines being used in the demonstration project are currently licensed in India and approved by Drug Controller General of India (DCGI) and at least 100 other countries, and are available in the private market. The vaccine has been licensed by Indian government. As of 2008, these vaccines have been recommended by advisory committees and MOH officials to be used in National Vaccination programs in over 22 countries. The Indian Academy of Pediatrics also recommends this vaccine to be given to adolescent girls and the members prescribe and the clients receive the vaccine in private sector.

WHO in its position paper mentions : "HPV vaccines are most efficacious in females who are naive to vaccine-related HPV types; therefore, the primary target population should be selected based on data on the age of initiation of sexual activity and the feasibility of reaching young adolescent girls through schools, health-care facilities or community-based settings. The primary target population is likely to be girls within the age range of 9 or 10 years through 13 years." (Source: Human papillomavirus vaccines: World Health Organization position paper. *Weekly Epidemiological Record.* 2009, 84:118-131. Available at: www.who.int/wer/2009/wer8415.pdf)

The Federation of Obstetrics and Gynecological Societies of India (FOGSI) and The Indian Academy of Pediatrics (IAP) also recommend the vaccines

Reference : www.fogsi.org/hiv_vaccine.html; www.iapcoi.com/hpv.htm

Vaccine effective for HPV 16 and 18 only

HPV (human papillomavirus) is the primary cause of cervical cancer. Of the 15 high risk (oncogenic) HPV types, two of them —HPV 16 and HPV 18—account for 70 percent of cervical cancer cases worldwide . Studies from India have reported a similar distribution among Indian women with cancer of the cervix (*Bhatla et al 2008, Bhatla et al 2006).* Among women not already infected, vaccines against HPV-16 and -18 have been at least 95 percent effective in preventing persistent HPV infection and 100 percent effective in preventing type-specific cervical lesions. It is true that other types of HPV cause cervical cancer, and that is why screening will continue to be needed. But vaccination will reduce the incidence of precancer, will relieve pressure on the screening system, and will help protect women who may not avail themselves of screening services.

References:
Bhatla Neerja, Dar Lalit, Kumar Raj et al- Human Papillomavirus Type Distribution in Cervical Cancer in Delhi, India. International Journal of Gynecological Pathology Vol. 25; No. 4, October 2006, Pages 398-402

Guinea Pig Syndrome

The PATH-ICMR demonstration project in Khammam district in AP is not a clinical trial. Similar studies are being conducted in Peru, Uganda and Vietnam but none of those countries has yet made any commitment to ongoing vaccination after the research is completed. We, and they, are simply preparing ourselves for the day when these vaccines become affordable – as they surely will – so that we will then know what to do. For effective cervical cancer control in the coming decades, countries must work **now** to develop and maintain screening programs with treatment for adult women and vaccination for adolescent girls. So the allegation of using girls as guinea pigs does not hold true

Cancer of the cervix can be prevented in two ways: (1) preventing initial HPV infection through vaccination and (2) screening for precancerous lesions and providing early treatment to prevent progression to cancer. A comprehensive disease control initiative—a combination of improved screening and treatment with effective HPV vaccination—has the best potential to significantly reduce the burden of cancer of the cervix relatively soon.

We agree wholeheartedly with the authors that it is imperative to make cervical cancer screening available to more adult women. There are promising screening technologies that are now available which are better than the traditional Pap test. State Government of Andhra Pradesh in collaboration with the Regional Cancer Center – MNJ Institute of Oncology and PATH will also be implementing **secondary prevention** pilot project in Tirumalyapalem block in the Khammam district of Andhra Pradesh. The objective is to establish population based screening and pre-cancer treatment services based on Naticnal Cancer Control Programme (NCCP) guidelines for Cervical Cancer prevention. The plan of action is ready to be implemented upon completion of training and equipment supply.

In summary, the authors base their passionate letter on an inaccurate assumption: that time-limited operational research projects represent a commitment by the government

the vaccine specific HPV types and the antibody levels were tenfold higher than following natural infection with HPV. The antibody levels correlates with vaccine efficacy and the current evidence does not indicate a reduced performance at eight years or indicate a need for booster doses.

Cost concerns

The letter also focuses on the cost of the vaccine in the private market and the cost-effectiveness of HPV vaccination. Again, no one would ever suggest that a Rs 3000/dose vaccine be introduced in the public sector in India. Once prices reduce substantially, however – either due to competition, local production or subsidization by organizations like the GAVI Alliance – the governments will be able to assess the cost-effectiveness of an affordable vaccine, and then decide whether to introduce the product or not. The demonstration project will generate important information about developing country demand for HPV vaccine, which will help manufacturers better assess their market opportunities and, we believe, lead them to better (lower) pricing decisions than they would otherwise make. India has similar experinace on cost reduction dynamics for newer and underutilized vaccines when introduced in public health system.

The study violates the guidelines for biomedical research of ICMR which states children should not be tested upon unless they stand to gain directly from the research

As stressed upon earlier PATH-ICMR's Post-licensure Observational Study of HPV vaccination in Khammam District, Andhra Pradesh is not a clinical trial. The HPV vaccines being used in the demonstration project are currently licensed in India and approved by Drug Controller General of India (DCGI) and at least 100 other countries, and are available in the private market. The vaccine has been licensed by Indian government. As of 2008, these vaccines have been recommended by advisory committees and MOH officials to be used in National Vaccination programs in over 22 countries. The Indian Academy of Pediatrics also recommends this vaccine to be given to adolescent girls and the members prescribe and the clients receive the vaccine in private sector.

WHO in its position paper mentions : "HPV vaccines are most efficacious in females who are naive to vaccine-related HPV types; therefore, the primary target population should be selected based on data on the age of initiation of sexual activity and the feasibility of reaching young adolescent girls through schools, health-care facilities or community-based settings. The primary target population is likely to be girls within the age range of 9 or 10 years through 13 years." (Source: Human papillomavirus vaccines: World Health Organization position paper. *Weekly Epidemiological Record.* 2009, 84:118-131. Available at: www.who.int/wer/2009/wer8415.pdf)

The Federation of Obstetrics and Gynecological Societies of India (FOGSI) and The Indian Academy of Pediatrics (IAP) also recommend the vaccines

Reference : www.fogsi.org/hiv_vaccine.html; www.iapcoi.com/hpv.htm

to long-term, routine, population-based HPV vaccination. While the authors undoubtedly are well-meaning, they fail to appreciate the seriousness of cervical cancer in India. It is to be hoped that there will be opportunities for future dialog with interested groups so that accurate information is shared and we can work together to achieve our shared goal of improving the health and survival of women in India.

Finally, should you wish us to respond to some other specific points made in the letter, we would be pleased to do so.

Sd/- Anil Chandra Punetha
Commissioner of Family Welfare

// Attested //

Joint Director (CH&I)