Centre halts HPV vaccine project

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NEW DELHI: In the wake of reports of violation of ethical guidelines and exploitation during the "clinical trials" of HPV (human papilloma virus) vaccine, meant to prevent cervical cancer among women, the Centre on Wednesday advised the State governments to suspend the vaccine programme until the issue is settled.

Director-General of the Indian Council of Medical Research V. M. Katoh told The Hindu that he had asked the Health Ministry, the State governments and the people not to go ahead with the programme. "There can be no compromise, if ethical issues have been violated by any non-governmental organisation or pharmaceutical company."

"I am not prematurely judging that the NGO is at fault, but if there are allegations, they need to be investigated, and concrete evidence has to be brought to our notice. But, until this happens, the programme needs to be suspended," he said.

CPI(M) MP Brinda Karat said it was important to know what would happen to those who were already vaccinated.

Explaining that the ICMR was only "technical facilitator," Dr. Katoh said a memorandum was signed with PATH-International in February 2007 for a project allotted to it by the Bill and Melinda Gates Foundation for assessing the feasibility of introducing HPV vaccine in India. Merck and GSK were to provide the vaccine and ICMR helped in protocol preparation.

Initially the NGO conducted a survey of the social acceptability of the project with the help of a questionnaire among the socially disadvantaged groups, as cervical cancer occurred more among the women from the disadvantaged sections with less health facilities and low capacity for buying expensive drugs. By the time the trial ended, the Drugs-Controller of India gave approval for marketing the two vaccines.

Pointing out that the trial started after approval from the State Advisory Committees and the ethical committees of the Andhra Pradesh and Gujarat governments and the National Technical Advisory Group as per the agreement with the NGOs, Dr. Katoh said: "Everything was going fine until we received complaints of violation of guidelines and exploitation of people from civil society groups some months ago following the death of four girls who were given this vaccine."

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