

## Notice to Centre on unethical clinical trials

**NEW DELHI:** The Supreme Court on Monday sought the Centre's response on a public interest litigation (PIL) alleging that unethical clinical trials of human papilloma virus (HPV) vaccines were conducted by an international NGO working in collaboration with Indian Council for Medical Research (ICMR) during 2009-10 in Andhra Pradesh and Gujarat.

A bench of Chief Justice P Sathasivam and Justice Ranjan Gogoi also issued notice to the NGO, the Program for Appropriate Technology in Health (PATH), on the petition filed by a group of NGOs, including Drug Action Forum from Karnataka, working towards health and women issues.

The bench tagged the case with other petitions on clinical trials being heard by a different bench.

According to the petitioner, there were "serious failures" on the part of the PATH and the ICMR in complying with legal and ethical requirements to obtain written "informed" consent and that caused serious adverse events.

"The Ethics Committees failed in their duty to protect the rights of trial participants by allowing the trial to be conducted on young girls from socio-economically backward families and where medical facilities were poor or non-existent," the petition said.

"The current ethical and legal framework to protect subjects of clinical trials is grossly inadequate and needs to be re-examined," the petition said. Senior advocate Anand Grover appeared on behalf of the petitioners.

The apex court in January gave a notice to the Centre on a PIL seeking direction to cancel licence of two vaccines, which had been used on 24,000 tribal women in Andhra Pradesh and Gujarat for treatment of cervical cancer, on the ground that their efficacies were not known.

Petitioner Kalpana Mehta and other health activists had alleged that the vaccines - Gardasil and Cervarix - are unproven and hazardous.

They had also claimed human papilloma virus (HPV) vaccines were being marketed in India by MSD Pharmaceuticals Pvt Ltd and GlaxoSmithKline Ltd.

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