

Apex court: Stop using Indians as guinea pigs

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Bangalore: The government seems to be taking serious and strict actions against unauthorized clinical trials. After over 2,242 deaths during clinical trials in the last five years, the government plans to regulate the \$500 million sector by bringing changes in drug laws to make lapses by pharma MNCs a punishable offence and enhance compensation among other steps.

The Supreme Court of India rapped the Health Ministry last week for allowing Indians to be used as "guinea pigs" in the conduct of drug trials. The ministry under the new rules will put specific responsibility on investigators and sponsors of drug trials, making it mandatory for them to address issue of medical management of subjects involved in trials in case of serious adverse events such as deaths.

The new rules will also prescribe a formula providing for higher compensation in case of serious adverse events such as death during the trials and fix a minimum compensation amount.

The Supreme Court on January 7, 2013 issued a notice to the government on a public interest litigation (PIL), which alleges that pharma giant GlaxoSmithKline (GSK) had conducted unauthorized trials of its vaccine on tribal girls.

The petition says that pharma company tested the vaccine for cervical cancer on 24,000 tribal girls in Andhra Pradesh and Gujarat. The PIL also alleges that testing had an adverse effect on the girls' health and that the pharma company didn't bother to give treatment to the affected. Seven girls are alleged to have died as a consequence. The apex court has directed that the Christian Medical College, Vellore, India, should be asked to examine the medical records of the girls in

question and submit a report to the court.

In an email response to *BioSpectrum*, the spokesperson informed that "At this stage it would be inappropriate for us to comment anything on the matter since it is sub judice and pending before the Supreme Court, we understand that we have been made party in the proceedings but no papers have yet been served on us; once we receive the papers we would be filing our reply before the Supreme Court."