India tightens clinical trial regulations

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[NEW DELHI] Following criticism over a spate of patient deaths from adverse events during clinical trials, India has begun tightening up rules for clinical research and compensation as well as expanding its pool of medical experts.

Proposed amendments to existing laws, pending in Parliament since 2007, are to be withdrawn and redrafted to make approvals for clinical trials tougher, a health ministry official told *SciDev.Net*.

According to the ministry, 1,144 deaths were reported during clinical trials in 2010 and 2011. Of these, compensations were paid out in 22 cases.

In August, the Central Drugs Standard Control Organisation (CDSCO) – which approves manufacture and import of drugs as well as clinical trials – announced expansion of its pool of experts in various fields of medicine to ensure transparency, accountability and consistency in the approval process.

Already the CDSCO has asked ethics committees for tougher inspection regimes.

In August, CDSCO also issued guidelines on compensation to be paid in case of clinical trials-related death or injury.

These steps follow the report of a parliamentary committee, in May 2012, which found that a large number of imported drugs had been cleared without trials. These included drugs that had failed to be cleared for use in the parent countries.

The committee pointed out that the office of the Drug Controller General of India does not have its own medically qualified personnel, and was forced to seek opinion on safety and efficacy of new drugs from third parties. "Strangely, in 64 per cent of cases, such opinion was not obtained," the report of the committee said.

Amulya Nidhi of the Swasthya Adhikar Manch, a civil society organisation which has petitioned the Supreme Court for rectification of gaps in existing laws on injury and compensation and in the regulation of contract research organisations (CROs), says only parliamentary legislation can ensure fairness to people undergoing clinical trials.

Nidhi told *SciDev.Net* said that ethics committees set up to monitor the trials and CROs need to be made answerable to regulatory bodies.

The clinical trials registry, where every trial is registered for approval, does not have papers on the outcome of trials. The 22 deaths attributed to trials were paid a total compensation of just US$ 90,000, says Nidhi – making a case for changing the guidelines.

"We are not asking for a stoppage of the trials but there should be laws in place to ensure that CROs function in an ethical manner," he said.

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