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‘A heaven for clinical trials, a hell for India’: Court orders government to regulate drugs testing by international pharmaceutical companies

Court orders government to regulate medical testing amid fears over industry’s safety

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India’s highest court has given the government a month to come up with a plan to tighten regulations for clinical trials of new drugs – firing a warning shot at an industry that judges said has become a “hell for India”.

Amid claims that Indian citizens are being used as “guinea pigs” in an industry worth an estimated £310m a year, the Supreme Court told the government that no trials for new drugs should go ahead until a “mechanism is put in place to monitor them”. It said the health ministry should meet with regional officials within four weeks to discuss “strengthening the regulation of clinical trials”.

In recent years, India has emerged as one of the main locations for clinical trials by British, American and European pharmaceutical companies, looking for places to test new drugs and medicines. Hundreds of trials may be taking place at any one time.

But campaigners believe lax regulations have created a situation in India where those participating in the trials often have little idea about what they are doing. When things do go wrong, the authorities are slow to admit mistakes or to pay compensation. According to the Press Trust of India the Supreme Court bench, headed by Mr Justice RM Lodha, also called on the government to explain how it had approved 162 international trials to which it gave the go ahead between 3 July and 31 August this year. The government said it would suspend approval for these trials.

“We have asked the government for the details of the trials they have approved and how these trials have benefited India,” said Amulya Nidhi, of an Indian NGO, Swasthya Adhikar Manch, which had filed a legal action before the court.

Campaigners say many of the clinical trials that are carried out in India do not meet international standards. An investigation in 2011 carried out by *The Independent* highlighted the recruitment of hundreds of tribal girls for a study without parental consent, the use by drug companies of survivors of the world’s worst poisonous gas disaster without proper informed consent and tests carried out by doctors in the city of Indore that a police investigation found violated ethical guidelines.

Pushed by campaigners, the courts and the Indian authorities have slowly been acting to tighten regulations.

This summer, the Supreme Court claimed the government was in a “deep slumber” over the danger of clinical trials. Judge Lodha said that while foreign companies were treating India as a “heaven for clinical trials, it is proving hell for India”.

Just how many people may have been killed or seriously harmed by clinical trials remains uncertain. The government has testified that between 2005-2012, around 2,644 people died during clinical trials for new drugs, of which 80 deaths were directly attributed to the items tested. A further 500 suffered serious adverse reactions.

But campaigners say because it is often the doctors involved in the trials who have to determine whether or not the drug is responsible for a fatality, figures can sometimes be skewed.

Earlier this month, a parliamentary panel seriously condemned a trial for a drug against cervical cancer. The 2010 trials were carried out in conjunction with the state government of Andhra Pradesh and were led by a US-based NGO, Path, which received millions of dollars from the Bill and Melinda Gates Foundation. Seven people died following the trial of two drugs, one produced by the US company Merck and another by GlaxoSmithKline.

Investigators found no convincing evidence that the seven young women died from the drug but the parliamentary panel found the trials had failed to obtain consent from the parents of the hundreds of tribal girls involved in the tests. It said Path was being used as a tool by foreign drug companies who wanted their products taken up by the federal government.

In a statement about the report, Path said: "We strongly disagree with the findings, conclusions and tone of the released report and its disregard of the evidence and facts."

Industry estimates have suggested that the clinical trials industry in India could grow to £600m by 2016. But a recent flurry of interest by the courts appears to have spooked international drug firms.

It has been reported that as much as £100m of business could be lost this year because of uncertainty about the regulation environment.

"This has been a year of a lot of uncertainty in the clinical research industry," Suneela Thatte, president of the Indian Society for Clinical Research, told the *Mint* newspaper. "This has eroded the confidence of Indian and global bio-pharma companies, research and teaching institutions and not-for-profit organisations in doing clinical research in India."

Reports suggest up to 40 trials involving the US National Institutes of Health have been put on hold.

In a statement, a spokeswoman for the Washington-based NIH, said: "Because of the uncertainties posed by the new requirements, NIH and some grantees have suspended new patient enrolment for some of its ongoing interventional trials. Some NIH-funded trials and other planned activities have been postponed pending clarification of the new regulations."