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Don't allow clinical trials in absence of proper system: Supreme Court tells govt

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Don't allow clinical trials in absence of proper system: Supreme Court tells govt



While giving the judgment on September 30,2013 , the bench headed by Justice R M Lodha told that a system must be put in place to protect the lives of people and asked the Centre not to allow clinical trials for untested medicines.The judgment comes in the backdrop of hearing a Public Interest Litigation (PIL) filed by NGO Swasthya Adhikar Manch,that has alleged the large scale clinical drug trials across the country by various pharmaceutical firms using Indian citizens as guinea pigs in those tests.

The bench also directed the Centre to consider suggestions of various stakeholders in putting in place the mechanism to avoid any serious and adverse impact.

In a revised stance, the government officials as per sources assured the Supreme Court that Center will not allow clinical trials for 162 drugs permitted by it earlier.

The Supreme Court of India also earlier directed on the issue of clinical trials. It directed the Government to follow a certain mandatory standards for clinical trials of untested drugs on humans being.In an affidavit the Centre admitted that 2644 people died during clinical trials of 475 new drugs between 2005 -12.It also presented that during 2005 to 2012 serious adverse events of deaths during clinical trials of 2644 were 80 deaths.

The affidavit filed by the health ministry mentioned that an apex committee, headed by the secretary, helath and family welfare, has been formed to supervise the regulation of clinical trials based on the recommendation of the Technical Committee constituted under the chairmanship of the director general health services (DGHS).

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"It is submitted that the Drugs and Cosmetics (Amendment) Bill, 2013 has been introduced in Parliament. The Bill has a separate chapter containing penal provisions for violation and non-compliance of the provisions relating to conduct of the clinical trials," it said.

The Centre also told the apex court that central Drugs Standard Control Organisation (CDSCO) is being expanded and its strength will be increased from 327 posts with 169 drug inspectors to 1,102 during the 12th five tear plan.

It said that out of 89 cases of clinical trial death between 2005-12, compensation has been paid in 82 cases so far and the CDSCO is looking into rest of the cases.

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