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Indian government framing new clinical trial law

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Singapore: The Indian Supreme Court on July 26 heard a Public Interest Litigation (PIL) seeking a ban on drug trials in the country. The government has told the apex court of the country that a new law is being framed to regulate clinical trials in India.Ã?Â The National Institutes of Health (NIH), US, had recently cancelled 40 ongoing clinical trials in India. NIH had blamed the cancellations of the trials on the regulations that the Indian Government has formulated for its clinical studies.

In 2012, a total of 436 deaths during clinical trials in the country were recorded and 16 of these were directly related to drugs. Deaths owing to such trials and inadequate compensation had triggered much criticism and protests, forcing the government to put all the fresh trials on hold.

The court has asked the central government to call for a meeting of all the states within two weeks and decide on a mechanism to monitor such trials. The government is said to bring about some amendments to the laws that govern such trials in the country during the monsoon session of the Parliament.

The Indian Society for Clinical Research (ISCR) has stressed in a statement that in the larger context of India's unique healthcare requirements and the growing incidence of endemic diseases and emerging lifestyle diseases, the need for clinical research to develop new and effective medicines and vaccines to tackle our mammoth disease burden and unmet medical need. India has 16 percent of the world's population and 20 percent of the global disease burden and yet, less than two percent of global trials take place in India.

"ISCR is fully supportive of the initiatives undertaken to create a more robust and regulated environment in India for the conduct of clinical research, one which ensures the practice of the highest standards of ethics and quality and where patient rights and safety are protected. Any steps to ensure the practice of the highest standards of ethics and quality and the protection of patient rights and safety is welcomed by us," they said in the statement.