

Supreme court defers hearing on clinical trials

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Ongoing hearing of public interest litigation (PIL) filed by an NGO, Swasthya Adhikar Manch, that was supposed to come up for hearing today on August 25, 2014, has now been postponed for future date. The SC bench asked for few more days to go into the details presented by rival sides, before it hears the further arguments in this regard.

Earlier in April, 2014, the bench led by Justice Lodha had ruled for an additional triple-test for all global clinical trials and especially for cases involving new chemical entities. It had directed the government to ensure that three parameters - "assessment of risk versus benefit to the patients, innovation vis-a-vis existing therapeutic option and unmet medical need in the country" - are followed before approval for any global clinical trial.

"To obviate any controversy in future in this regard, we direct that henceforth in the format seeking information from the applicants, three specific columns regarding the above parameters shall be inserted for the purpose of New Clinical Entities/Global Clinical Trials," it observed.