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Drug Watchdog wants Mandatory Recording of Clinical Trial Consent

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The Drug Controller General of India (DCGI) has released draft guidelines that make it mandatory for clinical research organisations to conduct an audiovisual recording of the trial patients informing them about each and every risk involved while undergoing the trial. The measure, introduced in addition to the existing written consent forms, could bring in greater transparency and clarity in clinical trials.

According to the draft guidelines issued by the drug controller in response to a Supreme Court directive, this norm will also apply to the global trials conducted in India. In case the trial patient is not able to give informed consent, the investigators have to take the consent of a legally representative person.

"All clinical trials in addition to the requirement of obtaining written informed consent, audiovisual recording of the informed consent process of each trial subject, including the procedure of proving information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality. Such audiovisual recording and related documentation would be preserved," the drug controller said in its draft guideline.

The apex court had issued this directive so that any uninformed or false consent from patients enrolling into trials could be avoided. The directive came after the court heard a public interest litigation filed by the organisation Swasthiya Adhikar Manch, which alleged that the government was granting clinical trial approvals without following proper norms, as a result of which many patients were enrolled in trials without giving their consent. The measure will also apply to the new trials that got approval in the past one year.

"I think this is a welcome move. Those who have been conducting trials ethically are already recording the statements of the patients; this is a good documentary procedure," said Arun Bhatt, managing director of Clinvent, a clinical research company. This move will also help provide evidence against the patients who turn back on their consent after signing up for a trial, Bhatt added.

Patients will have to be informed about each and every risk involved while undergoing the trial

However, some fear that the additional requirement could be tedious and impractical.

"Companies can record consent. However, spelling out each and every detail of the trial procedure might scare off the patients who might decide to withdraw their participation in the trial. I think this guideline is impractical," said RK Shanghvi, chairman of the medical sub-committee of industry body Indian Drugs Manufacturers' Association.

The approval of clinical trials in India has become an emotive issue, with health activists claiming that pharma companies are unethically enrolling candidates for their research. The Supreme Court had last September halted the approval of more than a hundred trials in the country because it suspected they were not being conducted according to the norms.

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