CLINICAL TRIALS

Drug companies raise compensation concerns

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Should a patient participating in the research of a new drug be compensated if the medicine does not have the desired effect?

And is compensation necessary, even if the patient is part of the trial's placebo group? In a placebo, the patient is given no medicine or a dummy one, and hence, runs the risk of his/her existing disease progressing, or even death.

Some of these compensation-related clauses, notified in January by the Government, have been red-flagged by representatives of the drug industry in recent letters to the Prime Minister and Health Secretary.

The rules are not comparable with international standards and could bring clinical trials to a halt in the country, they caution.

Early next month, health authorities are scheduled to meet representatives from drug companies and clinical research organisations to discuss these concerns.

In an investigational drug, the research may or may not get the desired result, and that is the inherent risk of research, a representative with a drug major explained. The purpose of a clinical trial is to prove the therapeutic effect, she said.

A health activist, familiar with the development, said this industry grievance merits redressal. The operative part – that the subject participating in the clinical trial should be "adequately informed" – has been dropped in the final rule. Compensation comes in, if there is no informed consent.

A person needs to be informed before enrolling in a new drug trial, that they may not get the intended effect of the drug. And this could be the situation whether the person is given the investigational drug, or is part of the placebo trial.

Placebo trials are not gold-standard anymore, but they are used in new drug studies, when there is no existing drug to compare with, he said.

Clinical trials are under intense scrutiny, after pro-health groups took the issue to Supreme Court, seeking greater protection for patients participating in trials.

DOWN TO A TRICKLE

Industry representatives agree that drug companies should pay for drug-related fall-outs. But anything beyond that will discourage local companies from undertaking trials, they add.

Trials could move out to countries such as Malaysia and Thailand that are cost comparable, says Swati Piramal, Vice-Chairperson, Piramal Enterprises (that includes healthcare and research entities).

India would lose its advantage if local companies move out, she says, adding that the regulatory bottle-necks include time for approvals. In Canada, the US and Europe - it takes 28 days to get approvals for a trial, she said. In India, it could take up to nine months, or more, industry representatives say.

The bottleneck has to be resolved, as trials are reducing, says Arun Bhatt, President of ClinInvent Research, a contract research organisation doing clinical studies.

From 500-odd trials approved in 2010, and 262 in 2012, the Government says, six applications were approved in January.

The clinical research industry, tipped to touch $1.5 billion in 2010, was struggling at about $400 million in the last few years. It would barely be about $150 million now, he observed.

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