



## Strict Clinical Trial Rules will Drive Away Drug Firms: WHO

The World Health Organisation has informed India that its work in the country would be hampered and drug companies are driven away if the government goes ahead with stringent draft rules for compensation in case of death or injury from clinical trials.

### Background

- In 2013, 2,644 people died during clinical trials of 475 new drugs between 2005 and 2012. There were 11,972 serious adverse event cases in the same period. Of these, 506 cases were related to clinical trials.
- In February 2018, the Union Health Ministry released a proposal on clinical trials that included a provision for the deceased party in a trial to be compensated in event of any mishap.

### What has the Centre proposed?

- Drug firms to pay 60% of the compensation within 15 days if a patient dies or suffers disability in the course of a clinical trial.
- Compensation to be given taking into account the age, health risk of the patient.
- If a patient suffers from any other illness during the trial, the sponsor will provide medical management and ancillary care.
- The ethics committee will complete the probe within 30 days from the date of death of a patient or a serious adverse event or permanent disability suffered by him/her.

### Ethics Committee

- It is a proposed government body that will ensure medical experiments and research on humans are carried out in an ethical manner and provide feedback on the ethical appropriateness of the trial.
- It will consist of seven members, including experts from medical science, non-medical stream, scientific and non-scientific members, a layman and a woman member.

### Concerns of WHO

- Many sponsors of clinical trials are likely to consider the proposals harsh and unacceptable. Hence, there is a possibility that sponsors will not conduct clinical trials in India and go elsewhere.
- Also in a likely scenario whereby the ethics committee determines a death or permanent disability is related to the product - the 60% fee has to be paid upfront by the sponsor and is not reimbursable regardless of the decision of the expert review process.

