

New Math for Compensating Clinical Trial Deaths

DCCI has set ₹4-74 lakh as payout range, depending on age and health risks of volunteers at the time of enrolment

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New Delhi: India has become the first country in the world to start giving out compensations to victims of clinical trials on the basis of a formula that computes the sum after considering the age and health risk of the deceased.

About 21 compensations ranging from ₹4 lakh to ₹34 lakh have been given out by pharmaceutical companies this year to kin of people who were found to have died "due to" clinical trials on experimental drugs since January 2013, an official at the Drug Controller General of India (DCGI) said.

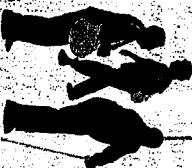
The decision on whether a death during a trial has been caused by the trial is being taken by an expert group constituted of clinicians and pharmacologists, part of a patient safety cell that DCGI's office has set up.

The expert group, which scammed through more than 160 cases of death, found that over 20 cases were caused by the trial. It is in the process of examining

Better Payment for Volunteers

Compensation's Criterion
A formula that computes the sum after considering the age and health risk of the deceased

Since January 2013,
21 compensations ranging from ₹4 lakh to ₹34 lakh have been given for such deaths



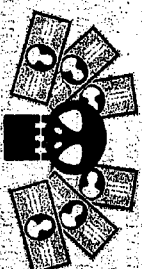
Expert group comprising clinicians and pharmacologists, part of a patient safety cell decide whether a death was caused by the trial

Of 160 cases 20
were caused by trial

110 more cases
under probe

From 2005 to 2012, pharma firms on average paid compensation of ₹1.5-4 lakh for such deaths

Word of Caution
Compensation is considered only in cases of death, though, not for non-fatal injuries that may result from trials



another 110 such cases. ET could not verify the names of the companies which have paid compensation to the next of kin of the victims.

This is part of the government's efforts to address concerns raised by health activists that pharmaceutical companies do not always adequately compensate volunteers of clinical trials who end up with injuries. The Supreme Court is currently hearing a public interest litigation on the matter. An ex-

pert committee set up by DCGI has set a range of ₹4-74 lakh as payout, depending on age and health risks of volunteers at the time of enrolment.

These figures are significantly higher than what some drug makers pay to trial victims in India.

From 2005 to 2012, pharma firms on average paid compensation of ₹1.5-4 lakh for clinical trial-related deaths, according to health ministry data.

"This mathematical formula is

based on a scientific methodology which will ensure complete transparency in the way compensation is calculated for clinical trial victims," said Drug Controller General of India GN Singh.

"India has taken the lead and has become a trendsetter by providing for such a formula, which will ensure rights of clinical trial victims are not compromised." The responsibility of ensuring that the amount determined is paid to a victim's entitled rela-

tive will lie with the pharma companies, or their representative in the country.

A healthy volunteer in the age group of 17-64 years with the least probability of dying due to medical complications at the time of recruitment will be entitled to the highest compensation.

The pharma firm will have to pay the compensation within 30 days of an order of the DCGI, but it will also have the option of appealing to the health ministry against the decision.

Of the 83 cases of trial-related deaths between 2005 and 2012, less than ₹2 lakh each has been paid out in 30 cases.

A compensation of ₹2-4 lakh has been given in case of 34 such deaths while ₹4-6 lakh has been given to 14 families. ₹6-10 lakh has been paid in two cases and over ₹10 lakh has been given as compensation in three cases.

The compensation is being considered only in cases of death, though, not for non-fatal injuries that may result from clinical trials.

Clinical Trials