

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:3106
ANSWERED ON:07.08.2015
Compensation for Clinical Trial Injury/Death
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Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the Government has finalized the draft guidelines for determining the quantum of financial compensation to be paid in cases of clinical trial related injury or death;
- (b) if so, the details thereof indicating the criteria adopted for deciding the quantum of compensation;
- (c) if not, the reasons for the delay in finalization of the guidelines; and
- (d) the time by which the said guidelines are likely to be finalized?

Answer

(a): Yes.

(b): (A) The criteria for deciding the quantum of compensation in case of Serious Adverse Event (SAE) of death related to clinical trial is as follows:

Compensation = B x F x R

$\hat{\Delta}$ 99.37

Where, B = Base amount (i.e. 8 lakh)

F = Factor depending on the age of the subject based on Workmen Compensation Act

R = Risk Factor depending on the seriousness and severity of the disease, presence of co-morbidity and duration of disease of the subject at the time of enrolment in the clinical trial between a scale of 0.5 to 4. However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of Rs.2.00 lakh is required to be given.

(B) The criteria for deciding the quantum of compensation in case of SAE of injury (other than death) related to clinical trial is as follows:

1. In case of Permanent disability:

Compensation = (C x D x 90)

100 100

Where, D = percentage disability the subject has suffered.

C = quantum of compensation which would have been due for payment to the subject's nominee(s) in case of death of the subject.

2. In case of Congenital anomaly or birth defect, the quantum of compensation would be half of the base amount as per formula for determining the compensation for SAE of death. In case of birth defect leading to deformity that can be fully corrected and permanent disability, the medical management is required to be provided by the sponsor or his representative in addition to the financial compensation.

3. In case of SAE causing life – threatening disease and reversible SAEs that are cured:

Compensation = 2 x W x N

Where, W = Minimum wages per day of the unskilled worker (in Delhi)

N = Number of days of hospitalization.

(c) & (d): Do not arise.