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CLINICAL TRIALS

■ Panel sends recommendations to the Drug Controller-General of India

erning council.

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The young and the healthy stand to get greater compensation if they suffer any untoward incident during a clinical trial. The expert committee working to determine the quantum of financial compensation to be paid in case of a clinical-trial-related injury decided that the compensation amount varying from a minimum of ₹4 lakhs to a maximum of ₹73.60 lakhs depending on the age of the deceased

and the risk factor. However, in case of patients whose expected mortality is 90% or more within 30 days, a fixed amount of ₹2 lakh should be given, the committee has opined.

The committee considered the Workmen Compensation Act that prescribes the factors (based on age) for calculation of the lump sum amount of compensation to be paid by the employer in case of permanent disablement and death depending upon age of the

injured. In the Act, the factor ranges from 99.37 (for age of 65 or more) to 228.54 (of age not more than 16) depending upon the age of the injured. After deliberations, the committee decided to apply the same factor for calculating the amount of compensation in case of clinical trial related death. The committee felt that the base amount should be such that if the nominee of the subject keeps that amount of compensation in bank by way of fixed deposit, he or she will get an monthly interest

amount which is at least approximately equivalent to the minimum wages of the unskilled workers. It was deliberated that the minimum wages as on date is ₹7,722 per month and accordingly, a base amount of ₹8 lakhs was approved. "It was also decided that this base amount should refer to the age of 65 yrs which corresponds to the factor of 99.37 of the table of Workmen Compensation Act," says the new rules. The base amount will

increase/change with the revision of minimum wage.

However, in case of patients whose expected mortality is 90% or more within 30 days, the committee decided that a fixed amount of ₹2 lakhs should be given.

The committee opined that the compensation amount will vary from a minimum of ₹4 lakhs to a maximum of ₹73.60 lakhs depending on the age of the deceased and the risk factor. However, in case of patients whose expected

mortality is 90% or more within 30 days, a fixed amount of ₹2 lakhs should be given.

The experts committee has sent its recommendations to the Drug Controller General of India (DCGI) and will have to be adhered to by the companies conducting clinical trials. For deciding on the formula, the committee decided that the criteria should not be discriminative in nature due to socio-economic conditions like income, educa-

Young, healthy stand to get better compensation

Regulatory
Clinical Trials.