

Pharma & Healthcare Update

August 24, 2012

FORMULA FOR DETERMINING THE QUANTUM OF COMPENSATION TO CLINICAL TRIALS SUBJECTS PROPOSED

The draft 'guidelines for determining the quantum of financial compensation to be paid in case of clinical trial related injury or death'¹ ("**Compensation Guidelines**") was recently released (August 2012) by the Central Drugs Standard Control Organization (CDSCO). The Ministry of Health and Family Welfare had, in November 2011, notified the draft rules for provision of compensation to research subjects for clinical trial related injury and death² ("**Draft Rules**"). The government felt the need to release the Draft Rules and the Compensation Guidelines since the existing law has been silent on the compensation front, except the Good Clinical Practices Guidelines which recommend financial compensation to research subjects for clinical trial related injury or death. A summary of salient features of the Draft Rules circulated by Nishith Desai Associates can be found [here](#). The Draft Rules have not been notified yet. The Draft Rules obligate the Sponsor of a clinical trial to financially compensate a research subject for a permanent injury or financially compensate the legal heir of a research subject in case of his death to the extent as recommended by the Institutional Ethics Committee ("**IEC**"). However, they do not provide for a method to calculate such compensation. This method is provided by the Compensation Guidelines. The Guidelines describe the scope of a few of the terms used in the Draft Rules, and lay down parameters which should be used in the process of determination of compensation.

1. Scope of application of the Compensation Guidelines

The Compensation Guidelines reiterate that the compensation provided will be over and above any expense incurred in the treatment of the research subject. However, this compensation is only in respect of 'loss of dependency to the family' of the injured or the deceased. It does not provide for compensation to the injured for loss of his capacity and incidental claims. The method for determination of the quantum of compensation will be applicable for any injury or death arising out of a clinical trial/study of drugs, including bioavailability/bioequivalence studies and trials of biological and medical devices. Injury, for the purpose of the Guidelines, has been described to include relatively minor harms (such as bruises or infected wounds), major injuries (such as organ damage or temporary disability) and fatal injuries (such as permanent disability or death). The Guidelines recognize that injuries could be physical as well as psychological or emotional in nature.

2. Method for determination of compensation

The Compensation Guidelines have fixed a standard formula based on four parameters. These parameters are: age, income, seriousness and severity of the disease which the research subject was suffering from at the time of his/her participation in the trial, and the percentage of permanent disability.

There are two sets of formulae provided under the Compensation Guidelines - first, the formula for calculation of compensation to the family in case of death of the research subject; and second, the formula to determine the compensation in case of injury arising to the study subject as a result of participation in the clinical trial.

1. The proposed formula for calculation of compensation to family in case of the death of the research subject is:

$$C1 = A \times B (1 - F/100)$$

Where,

C1 - The loss of dependency to family of the deceased research subject.

A - It denotes the contribution from research subject's salary to his/her family. The Compensation Guidelines have prescribed that contribution from salary to a family will

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comprise of that portion of salary which will be left after deduction of amount which the research subject would have spent on himself by way of personal and living expenses. This deduction has been fixed at 50% of salary in case of death, and 40% of salary in case of injury. The Compensation Guidelines further provide that in case the salary of research subject is less than the minimum wage stipulated under the Minimum Wages Act, 1948, then the nominal wage stipulated under that Act shall be construed as salary for the determination of contribution from the salary to the deceased's family.

B - It is a multiplier connected to the age of the research subject, provided in Annexure I³ of the Compensation Guidelines. The Compensation Guidelines state that this multiplier has been made considering several imponderables in life and economic factors.

F - It denotes the Risk Factor. The Risk Factor is a measure of seriousness and severity of a disease with which the deceased was infected at the time of participation in research, if any. The Risk Factor is evaluated in a scale between 0 - 100. Thus, a healthy research volunteer would have zero (0) as Risk Factor. The Compensation Guidelines limit the use of Risk Factor to fifty (50).⁴ It is the responsibility of the Investigator to evaluate and determine the Risk Factor.

2. The formula to determine the compensation in case of trial related injury is:

$$C2 = A \times B (1 - F/100) \times D/100$$

Where,

C2 is the loss of dependency to the family of the injured research subject.

A, B and **F** are the same as above.

D - Percentage disability caused to the research subject due to the clinical trial. The Compensation Guidelines do not stipulate who will determine the percentage of disability. However, it is commonly seen that a competent registered medical practitioner determines percentage disability.

The Compensation Guidelines provide the formula for determination of compensation in relation to any injury, including a temporary injury. This is inconsistent with the provisions of the Draft Rules, which provides for compensation only in case of serious effect on the health of the research subject as in the case of a permanent injury⁵ or on occurrence of a serious adverse event⁶.

The release of the Compensation Guidelines appears to be part of a larger plan of the Health Ministry to harmonize the law governing clinical trials in India. On July 17, 2012, the Government issued a draft notification proposing to amend the Drugs and Cosmetics Rules, 1945.⁷ This amendment seeks to insert an additional Rule in the Drugs and Cosmetics Rules, 1945 in relation to clinical trials. As regards compensation, the Rule provides that in case of study related injury or death, the applicant (sponsor of the clinical trial) will provide complete medical care as well as compensation for the injury or death and a statement to this effect is required to be incorporated in the informed consent document.⁸ It further provides that the details of the compensation, when given, will have to be intimated to the Drugs Controller General of India ("**DCGI**").⁹ By way of another draft notification dated July 17, 2012¹⁰, the Health Ministry proposes to make it mandatory for all IECs involved in a clinical trial to be registered with the DCGI. The notification fixes the term of registration of an IEC at 5 years from the date of registration. The DCGI has been accorded the power to suspend or cancel the registration of IEC if the IEC fails to comply with any of the conditions for registration.

Conclusion

The Compensation Guidelines and other notifications mentioned above are still in a draft form and comments have been invited from stakeholders within the prescribed period. Some aspects of the Guidelines may undergo revisions based on the comment received. Moreover, few aspects such as determination of compensation for injury or death in medical devices related clinical trials will require more clarity as the existing law concerning clinical trials of medical devices (whether regulated or unregulated) is not very well-defined.

Nonetheless, the Compensation Guidelines have provided a much needed preview of the manner in which compensation to research subjects in a clinical trial will be calculated in future.

Pharma Team

You can direct your queries or comments to the authors

¹ Available at <http://cdsco.nic.in/compention.pdf>

² Available at http://cdsco.nic.in/html/compensation_during_clinicaltrial.pdf

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³ The Annexure can be found in the Compensation Guidelines.

⁴ The Guidelines read as follows - "For the purpose of calculation of the compensation F should not be more than 50."

⁵ Rule 122 DAB(1)- In case of permanent injury occurring to the clinical trial subject as a result of his/her participation in the clinical trial, he/she shall be entitled for coverage of medical treatment, and financial compensation, as per recommendations of Ethics Committee.

⁶ See Appendix XII, Provision 5(4). It states that in case no formal claims have been made by the subject, the concerned Ethics Committee shall review the Serious Adverse Event and recommend compensation to be provided. A serious adverse event has been defined in the Draft Guidance for Industry on Reporting Serious Adverse Events Occurring in Clinical Trials issued by the Drugs Controller General of India as "an adverse event that is associated with death, inpatient hospitalisation (in case the study was being conducted on out-patients), prolongation of hospitalisation (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening."

⁷ Available at [http://cdsco.nic.in/572\(E\).pdf](http://cdsco.nic.in/572(E).pdf)

⁸ See Rule 122 DAC(1)(g).

⁹ Id.

¹⁰ Notification dated July 17, 2012 proposing an amendment to the Drugs and Cosmetics (4th Amendment) Rules, 2012 ("IEC Amendment"). Available at [http://cdsco.nic.in/573\(E\).pdf](http://cdsco.nic.in/573(E).pdf)

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