

Pharma & Healthcare Update

December 23, 2011

COMPENSATION FOR INJURIES IN CLINICAL TRIALS GETTING REGULATED ETHICS COMMITTEE DECISION FINAL

The Ministry of health and Family Welfare has proposed certain amendments to the Drugs and Cosmetic Rules, 1945 ("Drug Rules")¹ to ensure payment of compensation to the study subjects for study related injury or death on a timely basis. It was felt that the current law does not protect the interests of the study subjects adequately. The Government has invited suggestions and objection in relation to the proposed amendments by December 31, 2011.

Following are the salient features of proposed amendment:

- **Liability:** The liability to pay for medical treatment and financial compensation, as the case may be ("**Compensation**"), arises in case of (i) permanent injury to, or (ii) death of, the study subject, **as a result of his / her participation in the clinical trial**. However, it has been clarified that the liability will arise if the injury or death occurs due to the following reasons:

- o Adverse effect of investigational product(s),
- o Departure from approved protocol, scientific misconduct or negligence by Investigator, or Sponsor or local representative in the case of foreign sponsor or CRO,
- o Failure of an investigational product to provide intended therapeutic effect,
- o Administration of placebo providing no therapeutic benefits,
- o Adverse effects due to concomitant medication administered as per approved protocol,
- o Compensation to a child in-utero because of the participation of parent in a clinical trial

Throughout the proposed rules the terms "permanent injury" and "injury" have been used interchangeably. It should be clarified that the liability to provide medical treatment and financial compensation may arise only when there is permanent injury and in case of other injuries, the liability should be limited to provide medical treatment.

- **Entitlement:** In case of the injury the study subject and in case of death the legal heirs of the study subject shall be entitled to Compensation.

It is not stated, however, how the issue will be resolved, when more than one legal heir make a claim, the method of determining legal heirs etc. So as to avoid any issues, it should be clarified that the legal heirs who has/have been recognized through the letters of administration or succession certificate, as the case may be, should be entitled to receive the Compensation.

- **Entity liable to pay compensation:** (i) Sponsor, when sponsor is located in India; or (ii) in case of a foreign sponsor, local representative ("**LR**") or the CRO is liable to pay Compensation. Foreign sponsor is required to delegate the duty to pay Compensation to LR or CRO, as the case may be.

This is to ensure that the Indian regulators or parties entitled to Compensation are able to proceed against an entity in India, to recover the Compensation and are not required to approach foreign courts for the same. The LR or the CRO may then have back to back contract with the sponsor for recovery of the Compensation paid by them.

The amendment Rule mentions that the Sponsor may consider providing insurance coverage for unforeseen injury wherever possible. *It appears that obtaining of insurance cover is not mandatory.*

- **Changes in the Informed Consent Form (ICF) and other documents:** Prior to the commencement of the trial, Sponsor is required to provide an undertaking to the effect that it will provide Compensation in case of injury or death. Sponsor is required to provide the quantum of minimum Compensation for trial related injury or death in the Informed Consent Form. These details are required to be provided in the ICFs. Further, in the ICFs, address, occupation, qualification and annual income of the study subject is also required to be captured. The copy of the ICF is required to be provided to the study subject or his/her attendant.

- **The authority to decide Compensation:** The Ethics Committee is given power to decide and provide details of the Compensation to be paid. Decision of the Ethics Committee is stated to be final. However, if the study subjects / legal heirs are not satisfied with the decision of the Ethics Committee, then they may seek legal remedy through the courts.

Similar provision is not provided for in the event Sponsor / LR / CRO wish to challenge the order of the Ethics Committee.

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o **Sponsor:** Sponsor/ LR / CRO are liable to pay Compensation in the manner prescribed in Appendix XII. Within 90 of the submission of the Serious Adverse Event with the Drug Controller General's (DCGI) office, the Sponsor/ LR / CRO, are required to also submit the details of the Compensation paid for injury or death.

o **Investigator:** Investigator is required to provide information to the study subject through informed consent process regarding (i) various elements of clinical trial, (ii) his/her right to claim Compensation in case of trial related injury or death, (iii) his/her right to contact Sponsor / LR / CRO and Ethics Committee for the purpose of making Compensation claims. In case of injury, Investigator is required to request Ethics Committee to review and make recommendations for the payment for medical treatment as well as Compensation.

o **Ethics Committee:** Ethics Committee is required to review Serious Adverse Event and recommend the Compensation to the Sponsor / LR/ CRO, as the case may be.

· **Procedure for determination of Compensation:** Appendix XII is proposed to be added to Schedule Y of the Drug Rules, which describes the process for determination of the Compensation as follows:

o Within 30 days of receiving the notification of injury or death from the investigator, the Sponsor / LR/CRO should prove before the Ethics Committee that the injury / death is not on account of the clinical trial. Failing this, the Sponsor / LR/CRO shall be liable to provide Compensation as determined by Ethics Committee within 60 days.

It may not be possible to complete the process of determination of liability of Sponsor / LR / CRO within 30 days from notice of investigator. It should be clarified that within the said period of 30 days, Sponsor / LR/CRO should put its case before the Ethics Committee. Further, it should be clarified that the period of 60 days to pay the Compensation should be computed from the date of receipt of notice from the Ethics Committee.

o The study subject / legal heir may make a claim through the investigator to Sponsor / LR / CRO or to Sponsor / LR / CRO directly. In the latter case, Sponsor / LR / CRO shall take up the matter with the investigator for authenticating the claim.

o Ethics Committee will determine the Compensation within 30 days of reference being made to it.

It is not clear as to who is required to make a reference to the Ethics Committee.

o In case no formal claim is made, on its own accord the Ethics Committee may review the Serious Adverse Event and recommend Compensation to be paid.

o The investigator is required to forward the recommendation of the Ethics Committee to Sponsor / LR / CRO.

o The claim made by subject is required to be settled within 90 days.

Again, it is not clear as to what would be the starting point of 90 day period.

o In case of dispute between the stakeholders regarding amount of Compensation etc. an appeal may be made to the Ethics Committee for review and re-consideration.

It would not be appropriate for the Ethics Committee to sit in appeal of its own decision.

The sequence of various steps in the process for determination of Compensation is not very clear and is likely to create practical difficulties.

· **Failure to pay Compensation:** In case of failure to pay the Compensation, the Licensing authority after giving an opportunity of being heard has the power to suspend or cancel clinical trial or restrict Sponsor or local representative or CRO to conduct any further clinical trial in India or take such action that it deemed fit under the rules. The CRO may be conducting several trials in India for different sponsors.

It is not clear whether the CRO would be permitted to carry out other unrelated trials. It would be prejudicial to the interests of the CRO if due to failure to pay for trial of one sponsor, it is stopped from conducting trials for other sponsors.

COMMENT:

It is a welcome move by the government to regulate compensation mechanism for injury during clinical trials. Considering the concerns the Government has regarding the Compensation for injury or death during clinical trials, Government is expected to expedite the process and amend the Drugs Rules soon. However, as stated above, there are some provisions that need to be clarified further. Based on the final Rules, the stakeholders will need to revisit the manner in which the documents are structured and liabilities and responsibilities are allocated amongst them.

- Dr. Milind Antani & Gowree Gokhale

1 compensation during clinical trial

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