Pharma & Healthcare Update

February 14, 2013

RULES FOR COMPENSATION IN CLINICAL TRIALS RELATED INJURY, DEATH NOTIFIED

On November 31, 2011, the Ministry of Health and Family Welfare ("**the Ministry**") had proposed certain draft amendments to the Drugs and Cosmetic Rules, 1945 ("**Proposed Amendment**") to ensure payment of compensation to the study subject ("**Subject**") for clinical trial related injury or death. These draft amendments were proposed as it was felt that the existing law did not protect the interests of the study subjects adequately. The Government had invited suggestions and objections in relation to the proposed amendments by December 31, 2011. Readers may remember that Nishith Desai Associates had provided its recommendations on the Proposed Amendment which can be found here. After more than a year, the final amendments have been notified, to be effective from January 30, 2013 ("**Amendment**"). The Amendment seems to have taken into account some of the recommendations made by the stakeholders.

The salient features of the Amendment have been captured below:
Clinical trial subjects are entitled to free medical management as long as required, and also are entitled to financial compensation for clinical trial related injury or death. In case of death of the subject, the compensation is payable to the nominee(s) of the subject.

What constitutes 'clinical trial related injury or death' has been laid out. Some of the provisions such as "failure of investigational product to provide intended therapeutic effect" have raised concerns.

The Sponsor or his representative ("**Sponsor Representative**"), whosoever has obtained permission to conduct the clinical trial in India, is obligated to bear the expenses of the Subject's medical management and provide financial compensation. With respect to the compensation, the Sponsor, whether a pharmaceutical company or an institution, is also required to give an undertaking to the Drugs Controller General of India ("**DCGI**") stating that it will provide compensation in case of clinical trial related injury or death.

'Serious Adverse Event' has now been defined for the purpose of Schedule Y (brought in from the definitions of 'Adverse Event' and 'Serious Adverse Event' set out in the Good Clinical Practice Guidelines).

A definite procedure for reporting serious adverse events and processing of incidental claims of financial compensation has been put in place. The Sponsor, Investigator and Ethics Committee have to submit their report with an analysis on the cause of the adverse event to the Experts Committee (in case of death and in case of injury, if the DCGI appoints such Committee) and the DCGI within a stipulated time. The Experts Committee to be set up by DCGI, would investigate the cause of death or injury (if required by DCGI), and recommend financial compensation, if applicable, to the DCGI.

The DCGI has been authorised to decide the cause of the serious adverse event as well as pass an order on payment of compensation, if applicable, taking into account recommendations of the Experts Committee.

The time frame for determination of the cause of serious adverse event and order of financial compensation is 3 months from the date of report of the serious adverse event by the Investigator.

The Sponsor or Sponsor Representative has been given a time frame of 30 days from receipt of the order of the DCGI to provide compensation to the Subject.

Failure of the Sponsor or Sponsor Representative to provide free medical management and/or financial compensation, as ordered, may lead to suspension or cancellation of the existing and further clinical trials in India.

The Informed Consent Form has been modified to include relevant details for the purpose of determination of compensation such as qualification, occupation and annual income of the subject. It is now obligatory to hand over a copy of the informed consent sheet and duly filled informed consent form to the subject or his / her attendant.

With multiple amendments being brought about in connection with compensation payable to the study subjects, there may be a feeling of unfairness and impracticality in implementing some of the provisions amongst the clinical trials industry. Some provisions may appear onerous as well while some other provisions appear to, yet, lack clarity. The process of determination of compensation has not taken into account the principles of natural justice. The right of Sponsor to receive the copies of the reports filed by Investigator, Ethics Committee or to be heard before the order is passed is not recognized.

For a detailed analysis on every provision of the Amendment, and our insights and recommendations, please write to us at pharmahotline@nishithdesai.com.

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