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31 clinical trial cases paid compensation in 2013

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The fear of negative coverage in media over the non payment of compensation to the victims as well as the repeated warnings by Drug Controller General of India's office worked well during year 2013. As many as 31 cases were paid the trials victims in cases involving deaths or serious adverse reactions. While activists will take the credit for this, companies have been insisting that they have been fair in following the guidelines in this direcion.

As per information available with the government, compensation in only three cases of SAEs of death related to Clinical Trial, one each for the years 2005, 2006 and 2010 has not been paid as the whereabouts of the legal heir could not be located. The information was given by the health minister, Mr J P Nadda in the Parliament recently adding further, "In terms of the provisions of the Drugs and Cosmetics Rules, 1945 as amended from time to time, every company or sponsor permitted to conduct Clinical Trials is required to pay compensation in all cases of Serious Adverse Events (SAEs) of injury or death, related to Clinical Trial."

The details of compensation paid in 2013 and 2014 in clinical trial related cases of SAEs of death reveal that during the year 2013, companies paid compensation worth more than Rs 2 crore to clinical trial voluteers for several adverse events during the trials. The biggest amount of Rs 34, 10, 200 was paid by Astellas for its drug Tacrolimus trials followed by Fortis CRO that paid Rs 21, 82, 800 for its issues with its Drug Eluting Stent. The third was PPD which had to shell out Rs 20, 07, 900 to patients for issues in trials of its product KIACTA.

At the same time, the compensation given in year 2014 was low perhaps due to lesser approvals to clinical trials in the country. During the previous year, Amgen and Novartis paid the amount of Rs 4,14,330 (for drug AMG 386 vs Placebo) and Rs 9, 52, 078 (for Enalapril/CLCZ696/Placebo) respectively to the patients.

Health minister further stated that the Rules 122DA, 122DAA, 122DAB, 122DAC, 122DD and 122E of the Drugs and Cosmetics Rules, 1945 specify the requirements for conducting clinical trials in India. Further, Schedule-Y of the Drugs and Cosmetics Rules, 1945 prescribes the responsibilities of the Sponsor, Investigator and Ethics Committee to protect the rights,

safety and well-being of clinical trial subjects. The measures taken in the recent past to strengthen the regulation of clinical trials include evaluation of the clinical trial proposals by the Subject Expert Committees/ Investigational New Drugs Committee, review of their recommendations by the Technical Committee and, thereafter, approval by the Apex Committee.

"Amendments have also been made in the Drugs and Cosmetics Rules, 1945 for safeguarding the rights, safety and well-being of trial subjects. Compensation is accordingly required to be paid in case of trial related injury or death within the prescribed timelines. Conditions such as requirements and guidelines for registration of the Ethics Committee have also been specified. It has been made mandatory for the sponsor or his representatives to furnish the details of the contract entered by the sponsor with the investigator with regard to financial support, fees, honorarium, payments, etc. Further, it has also been decided that with effect from 30.11.2013, in all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual informed consent will also be recorded in respect of each trial subject," said Mr Nadda.