GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:4945
ANSWERED ON:02.09.2011
PLACEBO CONTROLLED CLINICAL TRIALS
Bhagat Shri Sudarshan

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Government has recognised and accepted the Declaration of Helsinki regarding human experimentation developed for the medical community by the World Medical Association (WMA);

(b) if so, the details thereof and if not, the reasons therefor;

(c) the norms and procedures adopted for the placebo-controlled clinical trials and their application on the human beings in the above declaration;

(d) whether the Government has permitted placebo-controlled clinical trials in the country;

(e) if so, the details thereof during the last three years and the current year so far; and

(f) the number of deaths reported therein alongwith the compensation given in each of such cases, State/UT-wise?

Answer

THE MINISTER FOR HEALTH & FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a) & (b): Indian Council of Medical Research(ICMR) has prepared the ethical guidelines for biomedical research on human participants in 2000 and updated in 2006 which recognizes the Declaration of Helsinki in addition to other international guidances on Biomedical Research (Nuremberg Code, Universal Declaration of Human Rights, CIOMS guidelines, Belmont Report, Nuffield Council on Bioethics, WHO Guidelines etc.). ICMR ethical guidelines state that the use of placebo as described in Helsinki Declaration is being debated and the Declaration has not been helpful in providing clarity in this matter. ICMR guidelines further state that "each such protocol using placebo requires careful consideration before approval. Denial of available treatment to control (placebo) group of patients is unethical".

(c): As per Helsinki Declaration 2000, and its subsequent revisions upto 2008: The benefits, risks, burdens and effectiveness of a new intervention must be tested against those of the best current proven intervention, except in the following circumstances:

(i) The use of placebo, or no treatment, is acceptable in studies where no current proven intervention exists; or

(ii) Where for compelling and scientifically should methodological reasons the use of placebo is necessary to determine the efficacy or safety of an intervention and patients who receive placebo or no treatment will not be subject to any risk of serious or irreversible harm. Extreme care must be taken to avoid abuse of this option.

(d) & (e): Now all the clinical trials are required to be registered in ICMR clinical trial registry at www.ctri.in. As per CTRI database, number of placebo control trial registered is given below:

Between January, 2008 to December, 2010: 468 Between January, 2011 to 30.8.2011: 136

(f): The Serious adverse events (SAEs) of death may occur during clinical trials due to various reasons. These could be disease related deaths like cancer etc or administration to critical or terminally ill patients or side-effects or unrelated causes. Such deaths are investigated for causal relationship by investigator and by the medical experts of sponsor.

As per available data, the number of Serious Adverse Events of deaths in all clinical trials reported during the last three years viz. 2008, 2009 & 2010, were 288, 637 & 668 respectively. Further as per information made available by the sponsor /Clinical Research Organizations, compensation has been paid in 22 cases which were trial related deaths in 2010.