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Despite drop in clinical trials, strengthened regulations top priority: Govt

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The government on February 11, 2014 agreed that the number of clinical trial applications received by the Central Drug Standards Control Organization (CDSCO) has decreased over the period of time. The number of applications yearwise show the decline. While in the year 2011, the number of applications recieved were 306 and in 2012, these were 480 respectively. In comparison, the number in 2013 dropped down to 207.

Terming this as a result of stringent regulations, Mr Ghulam Nabi Azad, Union Minister for Health and Family Welfare told the Indian parliament that as per direction of the Supreme court dated October 21, 2013, it has been decided that for all clinical trials, in addition to the requirement of obtaining written informed consent, audio-visual recording of the informed consent process of each trial subject, including the procedure of providing information to the subject and his/her undertaking on such consent, is also required to be done while adhering to the principle of confidentiality.

"This is applicable to the new subjects to be enrolled in all clinical trials including Global Clinical Trials. As per the directions of the Hon`ble Supreme Court, the applications for conducting clinical trials are also being appraised through a three-tier mechanism - the New Drug Advisory Committees in CDSCO, a Technical Committee of experts, chaired by the Director General Health Services, and the Apex Committee, chaired by the Secretary, Health & Family Welfare," Mr Azad mentioned.

He also elaborated on the mandate of Drugs & Cosmetics Act & Rules made there under is to provide safe, effective and quality drugs and to protect the rights, safety and wellbeing of clinical trial participants. Clinical trials of "New drugs" are defined under the Drugs & Cosmetics Act & Rules. The requirements and the guidelines for undertaking clinical trials dated 30-01-2013 are specified in Rule 122 DA, 122DAA. Rules 122DAB, 122DAC, 122DB, 122DD were inserted to the Drugs and Cosmetics Rules via the following Gazette notifications:

(i)The Drugs and Cosmetics Rules, 1945 was amended vide Gazette Notification G.S.R. 53 E dated 30-01-2013 specifying procedures to analyze the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury of death as per prescribed timelines.

(ii)The Drugs and Cosmetics Rules, 1945 was amended vide Gazette Notification GSR 63(E) dated 01-02-2013 specifying various conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance.

(iii)The Drugs and Cosmetics Rules, 1945 was amended vide Gazette Notification GSR No. 72 (E) Dated 08.02.13 making registration of the Ethics Committee mandatory and specifying requirements and guidelines for registration of Ethics Committee.

Schedule 'Y' also mandates that clinical trial is conducted as per Good Clinical Practices (GCP) Guidelines issued by Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, Government of India.