GOVERNMENT OF INDIA
MINISTRY OF HEALTH AND FAMILY WELFARE
DEPARTMENT OF HEALTH AND FAMILY WELFARE

LOK SABHA
UNSTARRED QUESTION NO. 440
TO BE ANSWERED ON 03RD FEBRUARY, 2017

CLINICAL TRIALS INVOLVING BIRDS AND ANIMALS

440. SHRI B. SENGUTTUVAN:

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

(a) whether clinical trials using birds and animals at academic institutions need no clearance from the Drug Controller General of India and if so, the details thereof and the reasons therefor;

(b) whether the Ethics Committee at the respective academic institution gives the permission for the clinical trials; and

(c) the recommendations of the Ranjit Roy Committee in this regard?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI FAGGAN SINGH KULASTE)

(a): The term Clinical trial refers to the systematic study in human beings. Clinical trials can be conducted only after obtaining permission from the Drugs Controller General (India) (DCGI) and approval of the respective Ethics Committee. However, in case of clinical trials intended for academic purposes, no approval from DCGI is necessary. Preclinical studies are conducted on animals for development of new drugs. Permission from the DCGI for conduct of preclinical studies in animals is not required. The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) in the Ministry of Environment, Forest and Climate Change controls the conduct of experiments involving use of animals.

(b): In addition to seeking permission from the DCG(I) approval of the respective ethics committee(s) is also required to be obtained before conducting clinical trials.

(c): The Ranjit Roy Chaudhury Committee recommended that academic clinical research may be approved by institutional ethics committee. However, it also recommended that if a new drug or a new use for an existing drug is being evaluated, approval of the DCG(I) should be obtained.