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

LOK SABHA
UNSTARRED QUESTION NO. 1078
TO BE ANSWERED ON 29TH APRIL, 2016

CLINICAL TRIALS AT ACADEMIC INSTITUTIONS

1078. SHRI C.N. JAYADEVAN:

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

(a) whether the Government/Expert Committee has recommended for exempting the clinical trials conducted at academic institutions from taking mandatory permission from the Drug Controller General of India (DCGI);

(b) if so, the details thereof along with the major recommendations made by the Expert Committee;

(c) whether the Government has incorporated/implemented all these recommendations of the Expert Committee;

(d) if so, the details thereof; and

(e) if not, the reasons therefor and the time by which the same will be implemented?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) & (b): Yes. The Government has vide GSR No. 313(E) dated 16.03.2016 amended the Drugs and Cosmetics Rules, 1945 to *inter alia* provide as below:

"no permission for conduct of clinical trial intended for academic purposes in respect of approved drug formulation shall be required for any new indication or new route of administration or new dose or new dosage form where,-

(a) the trial is approved by the Ethics Committee; and
(b) The data generated is not intended for submission to licensing authority.

The Ethics Committee shall, however, inform the licensing authority about the cases approved by it and also about cases where there could be an overlap between the clinical trial for academic and regulatory purposes and where the said authority does not convey its comments to the Ethics Committee within a period of thirty days from the date of receipt of communication from the Ethics Committee, it shall be presumed that no permission from the licensing authority is required."

(c): Yes.

(d) & (e): Details have been provided in reply to part (b) above.