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

RAJYA SABHA
UNSTARRED QUESTION NO. 399
TO BE ANSWERED ON 25TH June, 2019

STRICT CLINICAL TRIAL RULES

399. DR. BANDA PRAKASH:

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

(a) whether the WHO has told Government that its work with India would be hampered and drug companies driven away if Government goes ahead with stringent draft rules for compensation in case of death or injury from clinical trials and asked to reconsider its decision;

(b) whether Government's proposals included a provision for the deceased party in a trial to be paid 60 per cent of the compensation within 15 days if the patient dies or suffers a permanent disability in the course of a trial; and

(c) whether Government has started deliberations and held meetings in this regard?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SHRI ASHWINI KUMAR CHOUBEY)

(a): Draft New Drugs & Clinical Trials Rules, 2018 were published on 01-02-2018 inviting public/stakeholder comments. In the light of certain provisions of the said draft Rules, WHO expressed apprehension that there was a possibility that sponsors may not conduct clinical trials in India.

(b) & (c): Yes. Subsequent to the deliberations and meetings on the Draft Rules, the New Drugs and Clinical Trial Rules, 2019 were notified on 19-03-2019.