

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

**LOK SABHA
UNSTARRED QUESTION NO. 2110
TO BE ANSWERED ON 29TH JULY, 2016**

LEGISLATION ON CLINICAL TRIALS

2110. SHRI PASHUPATI NATH SINGH:

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

(a) whether any legislation is being brought by the Government with regard to the clinical tests containing provision of punishment for the companies who involve in any malpractices, if so, the details thereof; and

(b) if not, the reasons therefor?

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

(a) & (b): Drugs & Cosmetics Rules, 1945 have been amended from time to time to ensure that the conduct of clinical trials does not compromise patient safety and welfare and at the same time, the approval process is not cumbersome and time consuming.

.....