

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

**LOK SABHA
UNSTARRED QUESTION NO. 3274
TO BE ANSWERED ON 5TH AUGUST, 2016**

ANIMAL TESTING OF NEW DRUGS

3274. SHRI G. HARI:

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

(a) whether the Government has banned the repeat animal testing of new drugs which were already tested abroad and if so, the details thereof; and

(b) whether the ban falls under the amendment schedule Y, and if so, the details thereof?

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

(a) & (b): The Government has vide GSR No. 313 (E) dated 16.03.2016 amended Appendix I to Schedule Y to Drugs and Cosmetics Rules, 1945 to *inter alia* provide that where data on animal toxicity as per specifications of Appendix III has been submitted and the same has been considered by the regulatory authority of the country which had earlier approved the drug, the animal toxicity studies shall not be required to be conducted in India except in cases where there are specific concerns recorded in writing.

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