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

RAJYA SABHA
UNSTARRED QUESTION NO.2377
TO BE ANSWERED ON 6TH DECEMBER, 2016

UK'S SUSPENSION OF MARKETING APPROVAL OF INDIAN DRUG

2377. SHRI ANAND SHARMA:

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

(a) whether Government is aware that UK's Medicines and Healthcare Regulatory Agency (MHRA) has suspended marketing approval for a widely used antibiotics that had won clearance based clinical trials conducted by India's Quest Life Sciences, due to concern over the integrity of trial data;

(b) if so, whether Government has ascertained the standards of the Quality Management System of Quest and other Agencies permitted to undertake clinical trials and recommends the drugs for approval; and

(c) whether MHRA decision impact the sale of Indian antibiotics?

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

(a): Yes.

(b): The Central Drugs Standard Control Organisation (CDSCO) had carried out inspection of clinical facility at Quest Life Sciences on 27th & 28th July, 2015. Based on the inspection report, and after considering the response of the firm to the show cause notice issued to them, the facility for conducting Bioavailability/Bioequivalence (BA/BE) studies was suspended on 10.11.2015 from for 15 days. Further, on the request of the firm for renewal of approval for conducting BA/BE studies, the facility was again inspected on 4th & 5th October, 2016 and the inspection team has recommended against renewal of approval.

(c): The impact of the decision taken by MHRA cannot be quantified. However, it can have some impact on exports.