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

RAJYA SABHA
UNSTARRED QUESTION NO.1388
TO BE ANSWERED ON 14TH MARCH, 2017

MEDICINES FOUND DEFICIENT BY DRUG CONTROLLERS

1388. SHRI HUSAIN DALWAI:

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

(a) whether many medicines made by private as well as Government pharmaceutical manufacturers have been found to be deficient by State Drug Controllers of various States in 2016;

(b) if so, the details for each such medicine along with their manufacturers and the reasons for deficiency and action taken against such companies;

(c) whether some of the manufacturers have alleged that the medicine tested was a fake medicine being sold under another brand;

(d) if so, what steps have been taken to check circulation of fake medicines; and

(e) whether drug regulators are suitably equipped to deal with the menace of substandard medicines?

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

(a) to (c): Samples of drugs are picked up by both the officers of Central Drugs Standard Control Organisation (CDSCO) and State Drugs Control Department regularly. Such samples are picked up as part of the surveillance activities and based on risks assessed. Complete details of the samples picked up by States/UTs are not maintained centrally. However, a nation-wide survey (2014-16) has been conducted in which 47012 samples were tested and analysed from across the country. The percentage of drugs not conforming to the prescribed standards (Not of Standard Quality) has been found to be 3.16% and that of spurious drugs 0.0245%. The entire report has been placed on the website of Ministry of Health & Family Welfare and CDSCO.

(d): Steps such as Risk Based inspections of manufacturing units to check compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) has been launched in 2016 and a comprehensive checklist has been prepared for ensuring compliance with GMP and GLP through self assessment.

(e): Both the enforcement and laboratory officials have been trained in various areas to enhance their capacity and state-of-the-art equipment has been provided to the drug testing laboratories. The strength of personnel in the regulatory structures has also been increased over a period of time. As a result, the drug regulators are better placed to discharge their responsibilities including dealing with substandard medicines.

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