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

LOK SABHA
STARRED QUESTION NO. 440
TO BE ANSWERED ON THE 16TH DECEMBER, 2016
INSPECTION BY DCGI

***440. KUMARI SUSHMITA DEV:**

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

(a) whether the Drug Controller General of India/Central drug regulator along with various State drug regulators have recently carried out inspections against several drug manufacturers for allegedly selling poor quality medicines and non-compliance of norms and if so, the details thereof;

(b) the details of action taken against such companies; and

(c) the steps proposed to be taken by the Government to ensure that the drugs meet the stipulated norms?

ANSWER
THE MINISTER OF HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

(a) to (c): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 440* FOR 16TH DECEMBER, 2016

(a) Based on the current Good Manufacturing Practices and Good Laboratory Practices under the Drugs & Cosmetics, Rules, 1945, the World Health Organisation, Good Manufacturing Practices and requirements in terms of Pharmaceutical Inspection Cooperation Scheme (PICS), the Central Drugs Standard Control Organisation (CDSCO) developed a comprehensive checklist for Risk Based Inspection of pharmaceutical manufacturing units in the country in 2016 and placed it in the public domain. Further, on the basis of a careful analysis of the risks involved, the CDSCO identified a number of companies manufacturing drugs in the country for being inspected in terms of the aforesaid criteria. Separately, one week training was imparted to the officers drawn from CDSCO, Drug Testing Laboratories and State Regulators. The trainees were subjected to assessment both before and after the training. A team of five officers each headed by a mid level officer were thereafter deputed to carry out inspections of indentified manufacturing units for a period of three days. So far, five rounds of such inspections involving 136 units have been carried out. The manufacturing units have also been advised to use the checklist for carrying out self-assessment and rectify deficiencies.

(b) The deficiencies noticed during these inspections have been shared with the manufacturing units and the State Licensing Authorities (SLAs). The manufacturing units and the SLAs have been advised to remove the deficiencies and also informed that further inspections are planned during 2017 to cross check action taken to rectify the deficiencies noticed during inspection. Manufacture of drugs is, in terms of the Drugs & Cosmetics Act, regulated by SLAs and, therefore, action against the manufacturers is required to be taken by the State Licensing Authorities. Details of action taken are not maintained centrally.

(c) Besides, the Risk Based Inspections, large number of samples of drugs are drawn for test and analysis. The regulators, the laboratory personnel both from the Centre and the States have been trained in modern techniques for ensuring the quality of medicines in the country. At the same time, the industry personnel have also been trained on various aspects of manufacturing of drugs including quality control. Such training programmes have been organized by the Indian Government/Regulator in association with WHO and other leading regulators of world. Penal action as per provisions of Drugs and Cosmetics Act, 1940 is taken in case of non-conformance with the Drugs and Cosmetics Act, 1940 and Rules thereunder.