GOVERNMENT OF INDIA
MINISTRY OF MICRO, SMALL AND MEDIUM ENTERPRISES

RAJYA SABHA
UNSTARRED QUESTION NO. 1712
TO BE ANSWERED ON 18.12.2023

MANUFACTURING OF SUBSTANDARD DRUGS BY MSMEs

1712. SHRI K. C. VENUGOPAL:

Will the Minister of MICRO, SMALL AND MEDIUM ENTERPRISES be pleased to state:

(a) whether Government has identified a huge number of pharmaceutical companies in the micro, small and medium enterprise (MSME) sector that are manufacturing substandard drugs;
(b) if so, the details thereof;
(c) the frequency with which Government assesses MSME-produced pharmaceuticals for quality, and the measures which are in place to ensure ongoing safety and efficacy; and
(d) the steps taken by Government to enhance regulatory frameworks and enforcement against substandard drug production by MSMEs, and the manner in which violators are being held accountable?

ANSWER

MINISTER OF STATE FOR MICRO, SMALL AND MEDMUM ENTERPRISES
(SHRI BHANU PRATAP SINGH VERMA)

(a) to (d): Ministry of Health and Family Welfare (MoHFW) is the administrative Ministry for regulation of drugs manufacturing. As per the information provided by MoHFW, under the Drug and Cosmetics Act 1940 and Rules, the regulatory control over the manufacture and sale of the drugs is exercised through a system of licensing and inspection by the State Licensing Authorities appointed by the State Governments. In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO) along with State Drugs Controllers (SDCs) have conducted risk-based inspections of 261 premises. During the inspection number of drug samples were drawn and tested. Certain samples have been found to be "not of standard quality". Based on findings, more than 200 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses/ product licenses etc., have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules 1945.

Ministry of Health and Family Welfare (MoHFW) and CDSCO have taken following regulatory measures to ensure the quality of medicines in the country:

i. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.
ii. States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.
iii. To ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs.
iv. Before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government and the applicants shall submit evidence of stability, safety of excipients etc., to the State Licensing Authority.

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