GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
STARRED QUESTION No. 180
TO BE ANSWERED ON THE 02ND AUGUST, 2024

Pharmaceutical Companies in MSME Sector

†*180 Shri Sanjay Haribhau Jadhav:
Shri Arvind Ganpat Sawant:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Government has taken note that a large number of pharmaceutical companies in Micro, Small and Medium Enterprises (MSME) sector have manufactured such drugs which have been identified as falling under 'Not of Standard Quality' (NSQ) criteria during risk based inspections of pharma companies conducted since December of the previous year;
(b) if so, the details thereof alongwith the reaction of the Government thereto;
(c) the action taken/proposed to be taken by the Government against the manufacturers of spurious drugs in the country;
(d) whether the drug regulator of the country had earlier pointed out the urgent need to review the present Good Manufacturing Practices (GMP) regulations and Quality Management System (QMS) being followed by pharma companies; and
(e) if so, the details thereof and the reaction of the Government thereto alongwith the action taken/proposed to be taken to review the present GMP regulations and QMS?

ANSWER

THE MINISTER FOR CHEMICALS AND FERTILIZERS & HEALTH AND FAMILY WELFARE
(SHRI JAGAT PRAKASH NADDA)

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

STATEMENT REFERRED TO IN REPLY TO PARTS (a) TO (e) OF STARRED QUESTION NO. 180 FOR REPLY ON 02.08.2024

(a) to (b): In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization along with State Drugs Controllers (SDCs) have conducted risk-based inspections of 400 premises including MSMEs. The firms have been identified based on risk criteria like number of drugs declared as Not of Standard Quality, complaints, criticality of the products etc. 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 of inspectors, more than 300 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.

(c): Under the Drug and Cosmetics Act 1940 and the Rules framed thereunder, 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. Licensee is required to comply with all the conditions of license including Good manufacturing practices (GMP) as prescribed under Drugs Rules, 1945. State Licensing Authorities are empowered to take action on violation of any conditions of such licenses including prosecution in appropriate Court of Law.

CDSCO and Ministry of Health and Family Welfare 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 speedy trial of offences under the Drugs and Cosmetics Act.
(iii). The number of sanctioned posts in CDSCO has been significantly increased in last 10 years.
(iv). 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.
(v). The Drugs and Cosmetics Rules, 1945 have been amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of the Central Government and the State Government.
(vi). The Drugs and Cosmetics Rules, 1945 have been amended, making it mandatory that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of manufacturing license by the Authority.
(vii). Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

(d) & (e): Under the Drug and Cosmetics Act 1940 and rules framed thereunder, 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. Licensee is required to comply with the conditions of license including Good manufacturing

practices (GMP) as prescribed under Drugs Rules, 1945. State Licensing Authorities are empowered to take action on violation of any conditions of such licenses including prosecution in appropriate Court of Law. As per the Drugs Rules, 1945 the manufacturing premises whether they are MSME or otherwise, are required to comply with the conditions of license including the Good manufacturing practices (GMP) as prescribed under the Schedule M of the Drugs Rules, 1945. Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the Schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products under Schedule M. Quality Management System (QMS) has also been prescribed in the revised schedule M.

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