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

LOK SABHA
UNSTARRED QUESTION NO. †1162
TO BE ANSWERED ON 09TH FEBRUARY, 2024

QUALITY AND SAFETY OF MEDICINES

†1162. SHRI GANESH SINGH:

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

(a) whether the Government has taken any measures to ensure the effective implementation of the standards prescribed by WHO for the pharmaceuticals in the country and if so, the details thereof;

(b) whether the Government proposes to strengthen the monitoring mechanism of the pharmaceutical supply chains particularly of those small production units which evade the regulatory inspections to ensure the quality and safety of the medicines in the country; and

(c) if so, the details thereof and if not, the reasons therefor?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a) to (c): Manufacturing, sale and distribution in the country are regulated by the State Licensing Authorities appointed by the respective State Government under Drugs and Cosmetics Act 1945 and Rules. Under the said rules manufacturers of drugs are required to comply with the requirements of Good Manufacturing Practices (GMP) as prescribed under Schedule M of the Drugs Rules, 1945.

As per the Drugs Rules, 1945 the manufacturers whether they are small 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. Further, 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.

As per the amendment, the revised Good Manufacturing Practices and Requirements shall come into force for manufacturers for implementation as under:

Category of manufacturers [Based on turnover (INR)]	Time line for implementation
Large manufacturers (Turnover > 250 crores)	Six months from the date of publication of these rules.

Small and Medium manufacturers (Turnover ≤ 250 crores)	Twelve months from the date of publication of these rules.

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 275 premises. 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. Based on findings of inspections, more than 250 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.

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