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

LOK SABHA
UNSTARRED QUESTION NO. 1505
TO BE ANSWERED ON 28TH JULY, 2023

DRUGS AND COSMETICS ACT, 1940

1505: Dr. PON GAUTHAM SIGAMANI:

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

(a) Whether the Government has asked regulatory authorities to conduct risk-based inspections and audits of the manufacturing plants to ensure the quality of pharmaceutical products in the country;
(b) if so, the details thereof;
(c) Whether it is a fact that 137 Pharmaceutical firms were inspected by the Government and action has been taken against the said firms;
(d) if so, the details thereof;
(e) Whether it is a fact that Schedule M has been considered to be made mandatory soon for Micro, Small and Medium Enterprises (MSME) Pharma firms under the Drugs and Cosmetics Act, 1940; and
(f) if so, the details thereof?

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

(a) to (d): Central Drugs Standard Control Organisation (CDSCO) in coordination with various State Licensing Authorities carries out joint inspection of pharmaceutical manufacturing units in order to assess their status of compliance, to the requirements of Good Manufacturing Practices (GMP) under the Drug Rules 1945, as per risk based approach.

CDSCO along with State Licensing Authorities have conducted risk-based inspections of 137 premises of pharmaceutical firms and based on findings, actions like issuance of stop production order, suspension, cancellation of licences etc., have been taken by the State Licensing Authority as per the provisions of the Drugs Rules, 1945.

(e) & (f): As per the Drugs Rules, 1945 the manufacturing premises whether they are Micro, Small and Medium Enterprises (MSME) Pharma firms or otherwise, are required to comply with the GMP as prescribed under the Schedule M of the Drugs Rules, 1945.

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