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

RAJYA SABHA
UNSTARRED QUESTION NO. 2678
TO BE ANSWERED ON 11TH AUGUST, 2026

PHARMACEUTICAL MANUFACTURING UNITS INSPECTED BY CDSCO

2678. SHRI MOHAMMED NADIMUL HAQUE:

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

(a) the number of pharmaceutical manufacturing units inspected by CDSCO since 2021;
(b) the number of such units found non-compliant with Good Manufacturing Practices; and
(c) the action taken in each case?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) to (c): The manufacture, sale and distribution of drugs are primarily regulated in the country under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder through a system of licensing and inspection by State Licensing Authorities (SLAs) appointed by respective State Governments.

As per the provisions of the Drugs Rules, 1945, drug manufacturing premises are inspected periodically to verify compliance with the requirements of Good Manufacturing Practices (GMP) prescribed under Schedule M. In addition to these statutory inspections, the Central Drugs Standard Control Organization (CDSCO) along with State Drugs Controllers (SDCs) have conducted Risk-Based Inspections beyond inspections of more than 1040 premises since December, 2022 and based on findings, more than 950 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses, warning letters have been taken by the State Licensing Authorities. More than 1100 cough syrup manufacturers have been subjected to intense audit in coordination with State authorities. Increased market surveillance sampling of syrup formulations by Central and State drugs regulators has also been done.

Further, with respect to number of non-compliant units and action taken in each case, CDSCO zonal offices forward the inspection report along with recommendation to the concerned State Licensing Authorities who are legally empowered to take actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses, warning letters including launch of prosecution in appropriate Court of law.

****