

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

**RAJYA SABHA
UNSTARRED QUESTION NO. 1870
TO BE ANSWERED ON 19TH DECEMBER, 2023**

INSPECTIONS OF MANUFACTURING SITES OF INDIAN PHARMA COMPANIES

1870: SHRI SAKET GOKHALE:

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

- (a) whether Government is conducting risk-based inspections through CDSCO of shortlisted "risky manufacturing sites" of Indian pharmaceutical companies, if so, the total number of shortlisted companies and grounds on which these companies have been shortlisted;
- (b) the current results and findings of these inspections, the number of shortlisted companies found to be deficient or have high rates of manufacturing Non-Standard Quality (NSQ) products; and
- (c) the number of Indian pharmaceutical companies found to be manufacturing non-standard or substandard quality products and the number of such companies shut down or blacklisted between the year 2016 till date?

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

(a) and (b): 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. 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 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.

(c): As per information received from various States/U.Ts Drugs Controllers, number of drug samples tested, number of drug samples reported Not of Standard Quality/ Spurious/ Adulterated from 2016 till date and enforcement action taken thereof is enclosed as Annexure.

Annexure

Number of samples tested and enforcement actions taken, no. of drug samples reported Not of Standard Quality /spurious /adulterated and enforcement action taken by States/UTs Drugs Controller since 2014

Year (1 st April of preceding year to 31 st March of following year)	No. of drugs samples tested	No. of drugs samples declared Not of Standard Quality	No. of drugs samples declared Spurious/ Adulterated	No. of prosecution launched for manufacturing, sale and distribution of spurious/ adulterated drugs	No. of persons arrested
2016-17	76,721	2,780	123	186	106
2017-18	82,599	2,783	236	131	163
2018-19	79,604	2,549	205	484	153
2019-20	81,329	2,497	199	421	220
2020-21	84,874	2,652	263	236	164
2021-2022	88,844	2,545	379	592	450
2022-2023*	89,729	2,921	422	642	262

* Data except from the State of Rajasthan