

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

**LOK SABHA
UNSTARRED QUESTION NO.1523
TO BE ANSWERED ON 10TH FEBRUARY, 2023**

DRUGS QUALITY CONTROL TEST

1523: SHRI DUSHYANT SINGH:

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

- (a) the instances and the details of drugs failing quality-control tests in the last eight years, year-wise;
- (b) whether it is a fact that neither the inspectors nor the State Drug Regulatory Authorities (SDRAs) are required to maintain a record of non-compliant and offending drug manufacturers; and
- (c) if so, the details thereof along with the reasons therefor?

ANSWER

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

(a) to (c): As per information received from various States/UTs Drugs Controller, year wise data of Not of Standard Quality/Adulterated/Spurious Drugs reported and enforcement action taken thereof in the last eight years (year wise) is **annexed**.

The manufacturing, sale and distribution of drugs in the country are regulated under the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945. The regulatory control over the manufacture, sale and distribution of drug in the country is exercised through a system of licensing and inspection by the State Licensing Authorities (SLAs) appointed by the respective State Governments. Manufacturers are required to comply with the conditions of Licence granted under the said Act and Rules to manufacture any drugs for sale and distribution in the country. The SLAs are legally empowered to take action of violation of any conditions of such licenses including prosecution in appropriate Court of law.

Annexure

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	No. of Raids Conducted
2014-15	74,199	3,702	83	152	85	14,042
2015-16	74,586	3,703	234	289	59	3,648
2016-17	76,721	2,780	123	186	106	10,921
2017-18	82,599	2,783	236	131	163	7,067
2018-19	79,604	2,549	205	484	153	33,492
2019-20	81,329	2,497	199	421	220	15,641
2020-21	84,874	2,652	263	236	164	20,922
2021-22	88,844	2,545	379	592	450	15,973
