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

LOK SABHA
UNSTARRED QUESTION NO. 1651
TO BE ANSWERED ON 11th FEBRUARY, 2022

MANUFACTURING OF FAULTY AND ADULTERATED DRUGS

1651. SHRI LAVU SRI KRISHNA DEVARAYALU:

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

(a) whether the Government is taking any steps to combat the manufacturing of faulty and adulterated drugs, if so, the details thereof and if not the reasons therefor;

(b) the steps taken by the Government to improve manpower in the area of drug regulation, i.e. drug regulators and the details thereof;

(c) whether the Government has taken measures to combat the huge time gap between the sale of faulty drugs in the market and the notification given for recall of the batch, if so, the details thereof and if not, the reasons therefor; and

(d) whether the Government has any data on the number of faulty drugs manufactured in the last five years, if so, the action taken against the manufacturers in such cases?

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

(a) to (c): The manufacture, sale and distribution of drugs in the country is regulated under the provisions of Drugs & Cosmetics Act, 1940 and its Rules through a system of licensing and inspection. Licenses for manufacture, sale and distribution of drugs are granted by the State Licensing Authorities (SLAs) appointed by respective State Governments. SLAs are legally empowered to take stringent action against violation of provisions of the Act and Rules.

The licensees are required to comply with all the conditions of license and follow Good Manufacturing Practices (GMP) of Drugs Rules to ensure that the drugs manufactured by them are safe and of standard quality.

The Government has taken a series of measures including strengthening of legal provisions, workshops and training programmes for manufacturers and regulatory officials and measures such as risk based inspections.

Further, under the Centrally Sponsored Scheme for 'Strengthening of the States' Drug Regulatory System', funds have been released for upgrading of existing State Drugs laboratories, setting up of new drug testing laboratories and upgrading of existing State Drugs Control Offices.

(d): As per information received from various State/UT Drugs Controllers, number of drugs samples tested, number of drugs samples declared sub-standard and spurious/ adulterated during the last five years are as below:

Year	**No. of drugs samples tested**	**No. of drugs samples declared not of standard quality**	**% No. of drugs samples declared not of standard quality**	**No. of drugs samples declared spurious/ adulterated**	**% No. of drugs samples declared spurious/ adulterated**	**No. of prosecutions**	**No. of persons arrested**
2016-17	76,721	2,780	3.6	123	0.16	186	106
2017-18	82,599	2783	3.36	236	0.28	131	163
2018-19	79,604	2,549	3.35	205	0.27	484	153
2019-20	81329	2497	3.07	199	0.24	421	220
2020-21	84874	2652	3.12	263	0.31	236	164

In respect of Zonal/Sub-Zonal offices of CDSCO, the information is as below:

Year	**No. of drugs samples tested**	**No. of drugs samples declared not of standard quality**	**% No. of drugs samples declared not of standard quality**	**No. of drugs samples declared spurious / adulterated**	**% No. of drugs samples declared spurious / adulterated**	**No. of prosecutions**	**No. of persons arrested**
2016-17	5207	146	2.80	NIL	0.0	21	NIL
2017-18	7088	381	5.37	2	0.028	17	6
2018-19	10382	310	2.98	5	0.048	31	4
2019-20	9299	307	3.30	12	0.12	28	6
2020-21	5460	170	3.11	3	0.055	12	NIL

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