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

LOK SABHA
UNSTARRED QUESTION NO. 410
TO BE ANSWERED ON 21ST JULY, 2023

CONTROL ILLEGITIMATE DRUGS

410: SHRI MOHAMMED FAIZAL P.P.:
SHRI BENNY BEHANAN:

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

(a) whether actions are being taken by the Government to control illegitimate drugs being circulated in the domestic market and if so, the details thereof;
(b) whether the recent deaths in Africa allegedly caused by India-produced medicines have affected the export of India′s medicine; and
(c) if so, the details thereof?

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

(a): Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken regulatory measures to ensure the quality of medicines in the country as below.

(i). The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Certain offences have also been made cognizable and non-bailable.

(ii). States/ UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.

(iii). The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been significantly increased in last 10 years.

(iv). To ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs.

(v). The Drugs and Cosmetics Rules, 1945 have been amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

(vi). The Drugs and Cosmetics Rules, 1945 have been amended, making it mandatory that the applicants shall submit evidence of stability, safety of excipients etc. to the State Licensing Authority before grant of manufacturing license by the Authority.

(vii). CDSCO coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

As per information received from various States/UT′s Drugs Controllers, number of drug samples tested, number of drug samples reported spurious/adulterated, sub-standard drugs and action taken against the offenders during last three years i.e. 2019-2022 is as below.

Number of samples tested and enforcement action taken, no. of drug samples reported Not of Standard Quality/spurious/adulterated and enforcement action taken by the States/UTs Drugs Controller and such information in respect of CDSCO during last three years is as below:

Year (1st April of preceding year to 31st 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
2019-20	81329	2497	199	421
2020-21	84874	2652	263	236
2021-22	88844	2545	379	592

(b) & (c): It is to mention that there has been substantial growth in export of India′s medicines as per information provided by Directorate General of Commercial Intelligence and Statistics.

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