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

LOK SABHA
UNSTARRED QUESTION NO.†4027
TO BE ANSWERED ON 24TH MARCH, 2023

PRODUCTION OF SPURIOUS DRUGS

†4027: KUNWAR DANISH ALI:

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

(a) the details of the medicines found harmful to health in the country during the last three years; and
(b) the steps taken/proposed to be taken to check recurrence of incidents similar to that happened in Gambia and Uzbekistan due to India made medicine?

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

(a) & (b): Isolated complaints regarding quality of drugs are received in Central Drugs Standard Control Organisation (CDSCO). As and when such complaints are received, the matter is referred to State Licensing Authorities (SLAs) for taking action as per the provisions of Drugs & Cosmetics Act, 1940 and Rules, 1945.

CDSCO and Ministry of Health and Family Welfare have taken regulatory measures to ensure the quality of medicines in the country as below:

1. 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. Serious offences have also been made cognizable and non-bailable.

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

3. The number of sanctioned posts in CDSCO has been significantly increased in last 10 years.

4. 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.

5. 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.

6. 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.

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