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

LOK SABHA
UNSTARRED QUESTION NO. 1853
TO BE ANSWERED ON 02ND AUGUST, 2024

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

1853. SHRI KOTA SRINIVASA POOJARY:

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

(a) whether the Central Drugs Standard Control Organization (CDSCO) lacks the necessary oversight to ensure that medicines manufactured in the country are safe and if so, the details thereof;

(b) whether CDSCO has recently released draft guidelines on good distribution practices to prevent the introduction of spurious, adulterated and sub-standard pharmaceutical products in the market and if so, the details thereof;

(c) whether generic medicines manufactured by some of the Pharma Companies despite having failed in quality tests are being sold in the markets across the country and if so, the details thereof;

(d) the number of drug samples tested and found spurious/adulterated, sub-standard drugs and the action taken against the offenders during the last three years, year-wise; and

(e) the regulatory measures taken/proposed to be taken by the Government to ensure the quality of medicines in the country?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) & (e): Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken various measures to ensure quality, efficacy and safety of medicines manufactured in the country. The key measures are as stated below;

(i). 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 400 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 300 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.

(ii). Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing

Practices and requirements of premises, plant and equipment for pharmaceutical products.

(iii). On 17-11-2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 1st of August, 2023 providing that the manufacturers of top 300 brands of drug formulation products, as specified in Schedule H2, shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

(iv). On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including unique product identification code, Batch Number, Manufacturing date, Expiry Date etc.

(v). On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that with effect from 01.03.2021 any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules.

(vi). 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.

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

(viii). The number of sanctioned posts in CDSCO has been significantly increased in last 10 years.

(ix). 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.

(x). 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.

(xi). 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.

(xii). Central regulator 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.

(b): Draft Guidelines on Good Distribution Practices for pharmaceutical products has been uploaded on the CDSCO Website (https://cdsco.gov.in) on 02nd April 2024 for ensuring quality of Drugs in the supply chain.

(c): In case of drug samples declared as Not of Standard Quality by the Drugs Testing laboratories under CDSCO, the respective manufacturing firms are asked for immediate recall and stop further distribution of the Not of standard quality Drugs in the market.

(d): As per information received from various States/U.Ts Drugs Controllers, number of drug samples reported Not of Standard Quality/spurious/adulterated and enforcement action taken by the States/UTs Drugs Controller during last three years is as under:

Year (April to March)	Number of drugs samples tested	Number of drugs samples declared Not of Standard Quality	Number of drugs samples declared Spurious/ Adulterated	Number of prosecution launched for manufacturing, sale and distribution of spurious/adulterated drugs
2020-21	84,874	2,652	263	236
2021-22	88,844	2,545	379	592
2022-23	96,713	3,053	424	663

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