GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 986
TO BE ANSWERED ON THE 12TH DECEMBER, 2023

Steps to control manufacturing of adulterated drugs

986 Shri Sandosh Kumar P:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether it is a fact that, out of 88,844 drug samples, 2,545 were declared unfit or not of standard quality and 379 samples were declared adulterated, during 2021-2022;
(b) if so, the details of the actions taken by Government against the manufacturers and distributors of such sub-standard medicines, if not, the reasons therefor;
(c) the details of the measures being undertaken by Government to ensure quality control standards of the medicines produced; and
(d) the details of the steps being taken to ensure strict compliance with good manufacturing practices by manufacturers, particularly the MSMEs?

ANSWER

MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS
(SHRI BHAGWANTH KHUBA)

(a) & (b): Ministry of Health and Family Welfare has informed that as per information received from State/UT Drugs Controllers, out of 88,844 drug samples tested, 2,545 were declared not of standard quality and 379 samples were declared spurious/ adulterated. Details of the actions taken by the Government against the manufacturers and the distributors of such sub-standard medicines from 2021 to 2023 are as under: -

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	No. of persons arrested
2020-21	84,874	2652	263	236	164
2021-22	88,844	2545	379	592	450
2022-23	*89729	2921	422	642	262

*Except from State of Rajasthan

(c) & (d): The Central Drugs Standard Control Organization (CDSCO) and the Ministry of Health and Family Welfare have taken regulatory measures to ensure the quality of medicines in the country. Details of such measures taken since 2021 are as follows: -

(i) On 17-11-2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E), coming into force from 1st of August, 2023, according to which 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.

(ii) 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.

(iii) The number of sanctioned posts in CDSCO have been increased from 111 in 2008 to 492 till January 2022. Further, 220 posts have been created on 16-06-2022 and 219 posts have been created on 13.07.2022.

The Central Regulator coordinates activities of State Drug Control Organizations 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.

Further, in order to assess the regulatory compliance of drug manufacturing premises in the country, CDSCO along with State Drugs Controllers (SDCs) have conducted risk-based inspections of 261 premises, and based on findings, more than 200 actions, like issuance of show cause notices, stop production orders, suspension, cancellation of licenses /product licenses etc. have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules 1945.

******