

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

**RAJYA SABHA
UNSTARRED QUESTION NO.934
TO BE ANSWERED ON 03RD DECEMBER, 2024**

ENSURING QUALITY AND SAFETY OF PHARMACEUTICALS

934: SHRI K.R.N. RAJESHKUMAR:

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

- (a) the measures being taken by Government to ensure that drugs produced by pharmaceutical companies meet the required safety and efficacy standards;
- (b) whether Government has conducted any review of the Drugs and Cosmetics Act to strengthen quality control regulations for pharmaceuticals; and
- (c) the steps taken to improve the functioning and capacity of the Central Drugs Standard Control Organization (CDSCO) to address quality control lapses?

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

(a) to (c): Drugs Technical Advisory Board (DTAB), a statutory body under the Drugs and Cosmetics Act, 1940, advises the Government on technical matters for administration of the Act. Based on the recommendations of the Expert Committees / DTAB, advice from State Drugs Controllers in Drugs Consultative Committee (DCC) meetings and comments from stakeholders, the Government considers amendments in the Drugs and Cosmetics Act, 1940 and Rules thereunder.

Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken several measures to ensure that the drugs produced in the country meet the required safety and efficacy standards and to improve the functioning and capacity of CDSCO, 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) had initiated risk-based inspections of Drug manufacturing firms from Dec 2022. Risk-based inspections of more than 500 premises have been conducted so far. Drug manufacturing 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 400 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. Revised Schedule M has become effective for the drug manufacturers with turnover > 250 crores from 29.06.2024.

- (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). 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.
- (ix). 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.
- (x). The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been significantly increased in last 10 years.
- (xi). Central government is providing regular Residential, regional training and workshops to CDSCO, State Drug Regulatory Authorities on Good Manufacturing Practices. In the training Financial Year 2023-24 CDSCO has trained 22,854 persons while in F.Y 2024-25 so far 13,007 persons have been trained.
