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

LOK SABHA
UNSTARRED QUESTION NO. †901
TO BE ANSWERED ON 07TH FEBRUARY, 2025

POOR QUALITY OF DRUGS

†901: SHRI BABU SINGH KUSHWAHA:

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

(a) whether the Government is aware that due to faulty drug manufacturing process poor quality drugs are being manufactured which may adversely affect the safety and health of patients and if so, the details thereof;

(b) the concrete measures taken/proposed to be taken by the Government to prevent the reduction of amount of active component in the drug and the use of toxic substances in spurious drugs;

(c) whether the Union Government has implemented any mandatory barcode of QR code system for pharmaceutical companies so that spurious drugs can be identified and prevented and if so, the details thereof; and

(d) whether the Government proposes to set up any inspection mechanism to ensure that all medicines should go through quality checks before being brought to the market and if so, the details thereof?

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

(a): Manufacturing, sale and distribution in the country are regulated by the State Licensing Authorities appointed by the respective State Government under Drugs and Cosmetics Act 1945 and Rules. Under the said rules manufacturers of drugs are required to comply with the requirements of Good Manufacturing Practices (GMP) as prescribed under Schedule M of the Drugs Rules, 1945.

Isolated complaints regarding quality of drugs are received from time to time. 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, as the SLAs are empowered to take action in case of any violation to the provisions of the said Act and Rules.

(b): Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken several measures to ensure quality, safety and efficacy of medicines in the country, 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> Rs. 250 crores from 29.06.2024. However, for manufacturers having turnover of less than Rs. 250 Cr, draft rules have been published vide GSR 10(E) dated 04.01.2025 regarding extension of timelines till 31st December, 2025.

(iii). 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.

(iv). 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.

(v). 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.

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

(vii). 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.

(viii). 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.

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

(x). 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.

(xi). Central government is providing regular residential, regional training and workshops to officials of CDSCO and State Drug Regulatory Authorities on Good Manufacturing Practices. In the Financial Year 2023-24 CDSCO has trained 22854 persons while in Financial Year 2024-25, so far 13007 persons have been trained.

(c): On 17.11.2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 01.08.2023 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. State Licensing Authorities are empowered under the said rules for effective implementation and monitoring, and in case of non-compliance to take action in accordance with the rules. Instructions have been issued to State Licensing Authorities to maintain a strong vigil to check compliance of the said requirement.

(d): Manufacture of drugs is regulated in the country through a system of inspection and licensing. As per one of the conditions of license, licensee is required to test each batch or lot of the raw material used by him for the manufacture of his product and also each batch of the final product and shall maintain records or registers showing the particulars in respect of such tests.

Further, as per provisions in revised Schedule M, quality control is the part of good manufacturing practices concerned with sampling, specifications and testing and with the organisation and documentation which ensure that the necessary and relevant tests are actually carried out and that materials are not released for use, nor products released for sale or supply, until their quality has been ascertained to be compliant with the requirements.

****