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

RAJYA SABHA
UNSTARRED QUESTION NO. 2839
TO BE ANSWERED ON 17TH MARCH, 2026

PRIOR APPROVAL OF DRUG QUALITY CHANGES

2839. SHRI JAGGESH:

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

(a) whether Government has made it mandatory for drug manufacturers to take prior approval from the regulatory agency in case of any change in the quality of drugs;

(b) whether the regulatory authority has issued specific guidelines regarding the type of post-approval changes that require manufacturer notification;

(c) whether Government plans to conduct risk-based audits and inspections to ensure compliance by manufacturing units with updated quality norms;

(d) whether the Drugs Technical Advisory Board and Drugs Consultative Committee have been directed to provide details of all post-approval changes to the licensing authority annually; and

(e) the details thereof?

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

(a) to (e): The Drugs Consultative Committee (DCC) under Section 7 of the Drugs and Cosmetics Act, 1940 is the advisory committee to advise the Central Government, the State Government and the Drugs Technical Advisory Board (DTAB) on any matter tending to secure uniformity throughout India in the administration of the said Act.

Based on the recommendation of 61st DCC meeting held on 01.06.2023, Drugs Technical Advisory Board in its 90th meeting dated 25.01.2024 deliberated the proposal to incorporate appropriate provisions under the conditions of license mandating manufacturers to provide the details of the critical/ major post-approval changes to the licensing authority and notify the licensing authority for small changes.

As a part of quality monitoring and in order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO), in collaboration with state regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. Firms have been identified based on risk criteria like number of drugs declared as not of standard quality, complaints, criticality of the products etc. As of now, CDSCO along with State Drugs Controllers (SDCs) have conducted risk-based inspections of more than 960 premises since December, 2022 and based on findings, more than 860 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses /product licenses, warning letters have been taken by the States/UTs as per the provisions of the Drugs Rules 1945.

Also, more than 1100 cough syrup manufacturers and 380 blood centres have been subjected to intense audit in coordination with State authorities. Increased market surveillance sampling of syrup formulations by Central and State drugs regulators has also been done.

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