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

LOK SABHA
UNSTARRED QUESTION NO. 4776
TO BE ANSWERED ON 20TH MARCH, 2026

STORAGE AND DISTRIBUTION STANDARDS FOR DRUGS

4776. SHRI AZAD KIRTI JHA:

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

(a) the existing legal and regulatory provisions to ensure the quality and integrity of drugs after manufacture, including during transit and storage at wholesale and retail premises;

(b) whether the Government has assessed gaps in the current regulatory framework relating to mandatory cold-chain facilities, humidity control and other storage conditions for different categories of drugs, particularly in view of India′s climatic and humidity variations and if so, the details thereof along with the reasons for not updating the regulations so far;

(c) whether the Government proposes to undertake reforms in line with the standards of the World Health Organization and if so, the details of the existing provisions governing such storage conditions along with the prescribed qualifications for persons operating wholesale and retail pharmacies;

(d) whether the existing qualifications and regulatory provisions are considered adequate as per modern practices and if so, the details thereof and if not, the reasons therefor along with the measures taken or proposed to be taken by the Government to strengthen them;

(e) whether the Central Drugs Standard Control Organisation (CDSCO) has issued any guidelines on distribution practices for drugs and if so, the current legal and implementation status thereof; and

(f) whether the Government proposes to provide statutory backing to such guidelines and if so, the details thereof along with the reasons for any delay in doing so?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE

(SMT. ANUPRIYA PATEL)

(a) to (f): The legal and regulatory provisions related to sale of drugs are provided under the Drugs Rules, 1945. The premises in respect of which the sale licence is to be granted shall

be adequate, equipped with proper storage accommodation for preserving the properties of the drugs as per the requirements.

As per Rule 64 and Rule 65 of Drug Rules, 1945 and conditions of license issued for wholesale/retail sale of drugs states that no drug shall be sold unless purchased under cash or credit memo from a duly licensed dealer or duly licensed manufacturer, enabling traceability.

Further, guidelines have been issued by Ministry of Health and Family welfare regarding storage, temperature monitoring and handling of vaccines during transit across all the rural as well as urban areas.

CDSCO has issued guidelines on "Recall and Rapid Alert System for Drugs" (including Biologicals & Vaccines). Further, draft Guidelines on Good Distribution Practices for Pharmaceutical Products is also published for ensuring quality of Drugs in the supply chain. These guidelines are available on website of CDSCO (www.cdsco.gov.in).

Further, a proposal for affixing bar code or quick response code on other drug formulation products was deliberated in the 90th Drugs Technical Advisory Board (DTAB) meeting held on 25.01.2024. The Board has agreed to the proposal to extend the provision of QR code to all vaccine products and to all antimicrobials, narcotic & psychotropic substances in a phase wise manner.

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