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

# LOK SABHA UNSTARRED QUESTION NO. 2191 TO BE ANSWERED ON 01<sup>ST</sup> AUGUST. 2025

# PUNITIVE MEASURE AGAINST PHARMACEUTICAL COMPANIES PRODUCING NSQ DRUGS

#### 2191. THIRU D M KATHIR ANAND:

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

- (a) whether any strict punitive measure is being proposed by the Government as a warning against Pharmaceutical companies whose products fail quality parameters and are declared as substandard and if so, the details thereof;
- (b) whether the Government is aware of the mushrooming of Pharma companies producing 'Not of Standard Quality' (NSQ) drugs and if so, the details thereof; and
- (c) whether the Central Drugs Standard Control Organization (CDSCO) has announced immediate suspension of product licences of companies found producing 'Not of Standard Quality' (NSQ) drugs by Government laboratories and if so, the details thereof?

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

(a) to (c): As per the provisions of the Drugs and Cosmetics Act, no person shall manufacture, sell, or distribute any drug that is not of standard quality, adulterated, or spurious. Any contravention of this provision constitutes a punishable offence under the said Act and The Act prescribes prosecution and penalty for the same.

Isolated cases of Not of Standard Quality (NSQ) drugs are reported from time to time. The samples failing in quality check are uploaded on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (<a href="www.cdsco.gov.in">www.cdsco.gov.in</a>), as part of the monthly drug alerts to make it available publicly.

In case of drug samples declared as NSQ by the Drugs Testing laboratories under CDSCO, the respective manufacturing firms are asked for immediate recall and stop further distribution of the not of standard quality drugs in the market. Further, based on investigation outcome, actions are taken by the licensing authorities concerned under the provisions of Drugs & Cosmetics Act & Rules made thereunder such as stop production orders, stop testing orders, license suspensions/cancellations, warning letters and showcause notices.

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