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

RAJYA SABHA
UNSTARRED QUESTION NO. 2524
TO BE ANSWERED ON 17TH DECEMBER, 2024

DIFFERENCE BETWEEN "SPURIOUS DRUGS" AND "NOT OF STANDARD QUALITY DRUG"

2524: SHRI S NIRANJAN REDDY:

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

(a) whether Government makes a distinction between "spurious drugs" and "not-of-standard quality drugs" and the details thereof;

(b) the measures that are in place to ensure that genuine pharmaceutical companies are not penalised for spurious drugs being manufactured in their name and the details thereof; and

(c) the status of the draft guidelines on product traceability and the details thereof?

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

(a): Standards of quality of drug are defined under Section 8 (for imported drugs) and Section 16 (for manufactured drugs) and Spurious drugs are defined separately under Section 9B (For imported drugs) and Section 17B (for manufactured drugs) of the Drugs and Cosmetics Act, 1940.

(b): In all cases of spurious drugs based on investigation, necessary actions are taken by licensing authorities concerned by prosecuting the offenders under the provisions of Drugs and Cosmetics Act, 1940.

(c): 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.

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.

****