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

RAJYA SABHA
UNSTARRED QUESTION NO.575
TO BE ANSWERED ON 07TH FEBRUARY, 2023

DETECTION AND PREVENTION OF SALE OF SPURIOUS DRUGS

575: SHRI M. SHANMUGAM:

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

(a) the highlights of the Report of the country-wide survey for spurious drugs;
(b) the details of action taken on the basis of the above Report;
(c) whether recently, various investigation agencies busted international syndicate manufacturing fake life-saving drugs; and
(d) if so, the details of action being taken to detect and prevent the sale of spurious and substandard drugs in the country?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(DR. BHARATI PRAVIN PAWAR)

(a): A National Drug Survey was conducted in the year 2014-16. Out of a total of 47012 drug samples drawn from both Government and private sources, the percentage of Not of Standard Quality (NSQ) and spurious drugs from Retail outlets was 3% and 0.023% respectively, while that from Government sources was 10.02% and 0.059% respectively.

(b): State Licensing Authorities (SLAs) are legally empowered to take stringent action against non-compliance of the provisions of the Drugs and Cosmetics Act and its Rules. Accordingly pursuant to report of the survey, the test reports of the drug samples declared as NSQ were forwarded to SLAs for taking necessary action.

(c): Central Drugs Standard Control Organisation (CDSCO) has informed that no such report has been received from investigation agencies busting any international syndicate.

(d): The Government has taken various regulatory measures to ensure the quality of medicines in the country. These includes notification for affixing Bar Code or Quick Response Code in Active Pharmaceutical Ingredients (APIs) and some drug formulations, increase in sanctioned regulatory posts of CDSCO and notification providing marketers of any drug to be responsible for its quality.

Further, testing capacities of Central Drugs Testing Laboratories under CDSCO have been strengthened, and Drugs and Cosmetics Rules, 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 product manufacturing license by the Authority, and that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of drugs falling under the Category II and Category IV of the Biopharmaceutical Classification System.

The Central Government has provided Rs. 651.97 crores for Strengthening the Drug Regulatory System including upgradation of existing State Laboratories, setting up of new Drug Testing Laboratories and upgradation of existing State Drug Control Offices as part of "Strengthening of State Drug Regulatory System".

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