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

RAJYA SABHA
UNSTARRED QUESTION NO.3120
TO BE ANSWERED ON 28TH MARCH, 2023

SPURIOUS DRUGS IN CIRCULATION

3120: SHRI RAJMANI PATEL:

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

(a) whether it is a fact that spurious and fake drugs and other health care products are available in a large scale in the country;
(b) if so, the percentage of spurious drugs and healthcare products that are in circulation in the country; and
(c) the steps Government has taken or propose take to combat and stop the sale of these drugs in the country?

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

(a) to (c): Isolated complaints regarding spurious drugs are received in Central Drugs Standard Control Organisation (CDSCO). As and when such complaints are received, based on merit, the matter is taken up by the CDSCO in coordination with State/UT Drugs Controller for action as per the provisions of the Drugs & Cosmetics Act, 1940 and the Drugs & Cosmetics Rules, 1945.

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. 665.05 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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