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

RAJYA SABHA
UNSTARRED QUESTION NO.1535
TO BE ANSWERED ON 20th DECEMBER, 2022

SUB-STANDARD MEDICAL PRODUCTS DURING COVID-19

1535: SHRI TIRUCHI SIVA:

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

(a) whether it is a fact that the incidents of sub-standard medical products increased by 47 per cent during the pandemic, i.e., 2020-2021 as per a report published by the Authentication Solution Providers' Association (ASPA);
(b) whether any investigation was conducted by Government with regard to the complaints of sub-standard medicines being provided to patients in hospitals;
(c) if so, the details thereof, and if not, the reasons therefor;
(d) whether Government plans to develop an authentication ecosystem to curb the circulation of sub-standard medicines in the market; and
(e) if so, the details thereof?

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

(a) to (c): As per information received from States/UTs Drug Controllers and Central Drugs Standard Control Organisation (CDSCO), 84874 drug samples were tested in 2020-21 out of which 2652 samples were declared Not of standard quality (3.12%), and 263 were declared spurious/ adulterated drugs (0.31%).

Complaints regarding quality of medicines, when received, CDSCO in coordination with State Licensing Authority takes action as per the provisions of Drugs & Cosmetics Act and Rules.

(d) & (e): 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. 647.47 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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