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

LOK SABHA
UNSTARRED QUESTION NO.4967
TO BE ANSWERED ON 31ST MARCH, 2023

DRUG REGULATORY SYSTEM

4967: SHRI JAI PRAKASH:

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

(a) whether the Government considers it appropriate to work together with States to remove loopholes in the drug regulatory system especially in the aftermath of two recent incidents reported from Uzbekistan and Gambia where it was alleged that medical products exported by two Indian firms to the two countries had certain contaminants which led to adverse reactions and death of some patients; and
(b) if so, the details thereof and if not, the reasons therefor?

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

(a) & (b): 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.

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.

CDSCO and Ministry of Health and Family Welfare have taken regulatory measures to ensure the quality of medicines in the country as below:

1. The Drugs and Cosmetics Act, 1940 was amended under Drugs & Cosmetics (Amendment) Act 2008 to provide stringent penalties for manufacture of spurious and adulterated drugs. Serious offences have also been made cognizable and non-bailable.

2. States/UTs have set up special Courts for trial of offences under the Drugs and Cosmetics Act for speedy disposal.

3. The number of sanctioned posts in CDSCO has been significantly increased in last 10 years.

4. To ensure efficacy of drugs, the Drugs and Cosmetics Rules, 1945 have been amended providing that applicant shall submit the result of bioequivalence study along with the application for grant of manufacturing license of oral dosage form of some drugs.

5. The Drugs and Cosmetics Rules, 1945 have been amended making it mandatory that before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

6. The Drugs and Cosmetics Rules, 1945 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 manufacturing license by the Authority.

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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