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

RAJYA SABHA
UNSTARRED QUESTION NO.2362
TO BE ANSWERED ON 21ST MARCH, 2023

MECHANISM TO MONITOR DRUG-MAKING UNITS;

2362: SHRI JAGGESH:

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

(a) whether it is a fact that the issue of substandard drugs will harm the reputation of the Indian pharma sector globally;
(b) whether Government had prepared an action plan for a nationwide inspection of drug-making units which are identified to be at the risk of manufacturing 'not of standard quality ' (NSQ)/adulterated/spurious drugs;
(c) whether Government proposes a permanent mechanism to monitor the process of inspection, reporting and subsequent action to ensure compliance to the Drugs & Cosmetics Act, 1940 and the Rules thereunder; and
(d) if so, the details thereof?

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

(a) to (d): Central Drugs Standard Control Organisation (CDSCO) in coordination with various State Licensing Authorities (SLAs) conducts inspections of pharmaceutical manufacturing units in order to assess the status of compliance, to the requirements of Good Manufacturing Practices (GMP) under the Drug Rules 1945, as per risk based approach.

There are laid down guidance and checklist for conduct of inspections to assess the compliance of manufacturing facilities with the specified GMP and Good Laboratory Practice requirements.

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. Certain 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.

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