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

LOK SABHA
UNSTARRED QUESTION NO. 3593
TO BE ANSWERED ON 21ST MARCH, 2025

EXPORT OF SUBSTANDARD DRUGS

3593. SHRI AMRINDER SINGH RAJA WARRING:

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

(a) the number of pharmaceutical companies investigated during the last three years (2022 23, 2023-24 and 2024-25) for exporting substandard drugs;

(b) the details of penalties imposed/legal actions taken against such companies;

(c) whether the Government is planning to impose any stricter liabilities on companies involved in regulatory violation and if so, the details thereof;

(d) the steps taken/proposed to be taken by the Government in the pharmaceutical industry to ensure greater accountability in production of quality and affordable medicines;

(e) whether the Government has received complaints/trade restrictions from foreign Governments in light of the quality of Indian pharmaceutical drugs; and

(f) if so, the specific concerns raised by the regulatory agencies in the importing countries regarding the Indian drugs?

ANSWER
THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE
(SMT. ANUPRIYA PATEL)

(a) to (f): The World Health Organisation, on an ongoing basis, issues medical product alerts as and when quality related incidents are reported to it by its member nations. Such alerts relate to incidents pertaining to various member nations, including India, and are accessible to the member nations. In addition, reports regarding quality concerns appear from time to time in sections of the media. Countries take action in respect of alerts etc. in accordance with their respective domestic law and systems.

In such cases, matters are referred to concerned Zonal/subzonal office of Central Drugs Standard Control Organisation (CDSCO) and investigated in coordination with the State Licensing Authorities (SLAs). Based on the investigations, SLAs take suitable action under the provisions of the Drugs and Cosmetics Act, 1940 & Rules made thereunder.

For export of drugs, the manufacturers are required to obtained license for manufacturing of the drugs from the concerned State licensing Authority (SLA) under the provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder. Further, the manufacturer is also required to comply with the requirements of the importing country.

Further, CDSCO and Ministry of Health and Family Welfare have taken following regulatory measures to ensure the production of quality medicines for all people across the country: -

(i) In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO), in collaboration with state regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. As of now, 905 units have been inspected, resulting in 694 actions being taken. These actions include Stop Production Orders (SPO), Stop Testing Orders (STO), license suspensions/cancellations, warning letters, and showcase notices, depending on the severity of non-compliance. This initiative has provided valuable insights into the ground reality of manufacturing practices and has led to relevant corrective actions, resulting in noticeable improvements in the regulatory framework.

(ii) Central Government has amended the Drugs Rules 1945 vide G.S.R. 922 (E) dated 28.12.2023 to revise the schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. Revised Schedule M has become effective for the drug manufacturers with turnover > Rs. 250 crores from 29.06.2024. However, for manufacturers having turnover of less than Rs. 250 crores, extension of the timeline for implementation have been granted till 31st December, 2025 vide G.S.R. 127(E) dated 11.02.2025.

(iii) On 17.11.2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 1st of August, 2023 providing that the manufacturers of top 300 brands of drug formulation products, as specified in Schedule H2, shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication.

(iv) On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including unique product identification code, Batch Number, Manufacturing date, Expiry Date etc.

(v) On 11.02.2020, the Drugs Rules, 1945 were amended vide G.S.R. 101 (E), providing that with effect from 01.03.2021, any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under these Rules.

(vi) 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.

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

(viii) 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.

(ix) 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.

(x) The number of sanctioned posts in Central Drugs Standard Control Organization (CDSCO) has been significantly increased in last 10 years.

(xi) Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee (DCC) meetings held with State Drugs Controllers for uniformity in administration of the Drugs and Cosmetics Act.

(xii) Central government is providing regular residential, regional training and workshops to officials of CDSCO and State Drug Regulatory Authorities on Good Manufacturing Practices. In the Financial Year 2023-24, CDSCO has trained 22854 persons while in Financial Year 2024-25, so far 13007 persons have been trained.

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