GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

RAJYA SABHA
UNSTARRED QUESTION No. 1303
TO BE ANSWERED ON 11TH MARCH 2025

Contribution to global drug supply

1303 # Smt. Sunetra Ajit Pawar:

Will the Minister of **Chemicals and Fertilizers** be pleased to state:

(a) whether Indian pharmaceutical industry, one of the largest industries in the world, is contributing significantly to global drug supply;
(b) if so, the global market share of the Indian pharmaceutical industry;
(c) whether the quality of these products has often been questioned in some global markets;
(d) if so, the facts thereof; and
(e) the steps taken to ensure quality and safety of Indian pharmaceutical products and to strengthen manufacturing practices?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a) and (b): As per a secondary market research analysis published by Bain and Company in the year 2025, Indian pharmaceutical exports ranked 11th globally in value terms in the year 2023 and accounted for 3% of the total pharmaceutical exports.

(c) and (d): 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.

(e): The Central Drugs Standard Control Organisation (CDSCO) and the Ministry of Health and Family Welfare have taken several measures to ensure the quality, safety and efficacy of medicines, as described below:

(i) In order to assess the regulatory compliance of drug manufacturing premises in the country, CDSCO, in collaboration with State regulators, initiated risk-based inspections of drug manufacturing and testing firms in December 2022. 905 units have been inspected, resulting in 694 actions being taken. Depending on the severity of non-compliance, the actions taken include orders to stop production, orders to stop testing, suspension or cancellation of licence and issuance of warning or notice to show cause. Risk-based inspections have provided valuable insights

into manufacturing practices being followed, led to corrective actions and resulted in discernable improvements in the regulatory framework.

(ii) The Central Government, *vide* its notification dated 28.12.2023, amended the Drugs Rules, 1945 to revise Schedule M to the said rules related to Good Manufacturing Practices and requirements of premises, plant and equipment for pharmaceutical products. From 29.6.2024, the revised schedule has become effective for drug manufacturers with turnover of over ₹ 250 crore. For manufacturers having a turnover of up to ₹ 250 crore, *vide* notification dated 11.2.2025, time for implementation has been granted till 31.12.2025.

(iii) To require manufacturers to print or affix on packaging labels of top 300 brands of drug formulation products bar code or Quick Response (QR) code that stores data or information legible with software application to facilitate authentication, the Drugs Rules, 1945 were amended through notification dated 17.11.2022, which came into force from 1.8.2023, to provide for such printing or affixation in respect of the drug formulation products specified in Schedule H2 to the said rules.

(iv) On 18.1.2022, the Drugs Rules, 1945 were amended to provide that every active pharmaceutical ingredient (bulk drug) manufactured or imported in India shall bear QR code on its label at each level of packaging, that stores data or information readable with software application to facilitate tracking and tracing. Such stored data or information shall include the minimum particulars, including unique product identification code, batch number, manufacturing date, expiry date, etc.

(v) On 11.2.2020, the Drugs Rules, 1945 were amended to provide with effect from 1.3.2021 that, along with the manufacturer, any marketer who sells or distributes any drug shall be responsible for the quality of that drug as well as other regulatory compliances under these rules.

(vi) The Drugs and Cosmetics Act, 1940 was amended through an amending Act of 2008 to provide for stringent penalties for manufacture of spurious and adulterated drugs. Certain offences were also made cognizable and non-bailable.

(vii) For speedy disposal of cases relating to offences under the Drugs and Cosmetics Act, 1940, State and Union Territory Governments have set up special courts.

(viii) To ensure efficacy of drugs, the Drugs Rules, 1945 have been amended to provide that applicants for grant of manufacturing license shall submit along with their application the result of bioequivalence study of oral dosage form of some drugs.

(ix) The Drugs Rules, 1945 have been amended to make it mandatory that applicants submit to the State Licensing Authority evidence of stability, safety of excipients, etc. before manufacturing license is granted by such authority.

(x) The number of sanctioned posts in CDSCO has been increased significantly over the last 10 years.

(xi) For uniformity in the administration of the Drugs and Cosmetics Act, 1940, the Central regulator coordinates activities of State Drug Control Organisations and provides expert advice through the Drugs Consultative Committee meetings held with the State Drugs Controllers.

(xii) The Central Government is providing regular residential, regional training and workshops to officials of CDSCO and State Drug Regulatory Authorities on Good Manufacturing Practices. Since April 2023, over 35,000 persons have been trained.

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