GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 719
TO BE ANSWERED ON THE 29TH NOVEMBER 2024

Substandard Drugs

719. Shri Anto Antony:
Smt. D K Aruna:
Shri Suresh Kumar Shetkar:
Shri Eatala Rajender:
Adv. Adoor Prakash:
Shri Kuldeep Indora:

Will the Minister of **CHEMICALS AND FERTILIZERS** be pleased to state:

(a) whether the Central Drugs Standard Control Organisation has found more than 50 drugs, including some batches of widely used antacids and paracetamol, to be substandard or fake, if so, the details thereof and the corrective steps taken in this regard, State-wise;
(b) whether the Government has taken any actions against the concerned companies, if so, the details thereof;
(c) the details of the steps taken by the Government to ensure the quality of medicines including medicines available in Jan Aushadhi centres;
(d) whether the Government noted that the circulation of counterfeit drugs is increasing in the country;
(e) if so, the details of measures taken by the Government for prevention of counterfeit drugs;
(f) whether the Government is planning to mandate QR code authentication for more drugs, if so, the details thereof; and
(g) the measures taken by the Government to ensure that it does not tarnish the reputation of the country as a reliable supplier of medicines on a global stage?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS & FERTILIZERS (SMT. ANUPRIYA PATEL)

(a) to (b): List of drugs of various companies, which are declared Not of Standard Quality/ Spurious Misbranded/ Adulterated by the Central Drugs Testing Laboratories is regularly uploaded and available on the website of Central Drugs Standard Control Organization (CDSCO) under the heading of Drug Alert (www.cdsco.gov.in). In the cases concerning quality or safety of drugs as and when reported, actions are taken by the concerned licensing authorities under the provisions of Drugs and Cosmetics Act 1940 and its Rules including prosecution in appropriate Court of law.

(c) to (g): Central Drugs Standard Control Organization (CDSCO) and Ministry of Health and Family Welfare have taken various measures to ensure quality, efficacy and safety of medicines manufactured in the country. The key measures are as stated below;

i. In order to assess the regulatory compliance of drug manufacturing premises in the country, the Central Drugs Standard Control Organization (CDSCO) along with State Drugs Controllers (SDCs) have conducted risk-based inspections of more than 400 premises. The firms have been identified based on risk criteria like number of drugs declared as Not of Standard Quality, complaints, criticality of the products etc. Based on findings of inspections, more than 300 actions like issuance of show cause notices, stop production order, suspension, cancellation of licenses/product licenses etc., have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules 1945.
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. As per the amendment, the revised Good Manufacturing Practices and Requirements shall come into force for manufacturers for implementation as under:

Category of manufacturers [Based on turnover (INR)}	**Time line for implementation**
Large manufacturers (Turnover> 250 crores)	Six months from the date of publication of these rules.
Small and Medium manufacturers (Turnover 250 crores)	Twelve months from the date of publication of these rules.

iii. On 17.11.2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) which has come into force from 1st 8 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 nonbailable.
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 before the grant of manufacturing license, the manufacturing establishment is to be inspected jointly by the Drugs Inspectors of Central Government and State Government.

x. 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.
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 CDSCO, State Drug Regulatory Authorities on Good Manufacturing Practices. In the training Financial Year 2023-24 CDSCO has trained 22854 persons while in F.Y 2024-25 so far 13007 persons have been trained.
xiii. Further, for strengthening the drug regulatory system in the country both at the Central and State level, the Government had approved Rs.1750 Crore. Out of this, Rs. 900 Crore was for strengthening the central drug regulatory structures and Rs. 850 Crore is for the Centrally Sponsored Scheme 'Strengthening of States' Drug Regulatory System (SSDRS) which envisages to strengthen the laboratory infrastructure and upgradation of existing State Drug Controller offices in States. So far under the SSDRS scheme, 17 New Drug Testing Labs have been constructed and 24 existing labs have been up-graded.

Apart from the above, Pharmaceutical and Medical Devices Bureau of India (PMBI) is the Implementing Agency of the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP). To ensure drug quality, PMBI procures medicines only from World Health Organization–Good Manufacturing Practices (WHO-GMP) certified suppliers. Each batch of drug is tested at laboratories accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL). Only after passing the quality tests the medicines are dispatched to Janaushadhi Kendras. PMBI also routinely audits vendors' facilities.

To ensure the supply and adequate availability of medicines at Janaushadhi Kendras, PMBI has set up a strong network of five warehouses located at Gurugram, Bengaluru, Chennai, Guwahati, and Surat and 36 distributors across the country. PMBI has implemented an Information Technology (IT) enabled end-to-end supply chain system and SAP-based inventory management system.

Further, Minimum Stocking mandate has been implemented for Pradhan Mantri Bhartiya Janaushadhi Kendras. Stocking mandate requires availability of 200 medicines at theses Kendras, which covers top 100 selling medicines of PMBJP product basket and 100 fast selling medicines in the market.

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