GOVERNMENT OF INDIA
MINISTRY OF CHEMICALS AND FERTILIZERS
DEPARTMENT OF PHARMACEUTICALS

LOK SABHA
UNSTARRED QUESTION No. 2246
TO BE ANSWERED ON THE 12th DECEMBER, 2025

Quality Concerns of Medicines at Jan Aushadhi Kendras

2246. Thiru Dayanidhi Maran:

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

(a) whether the Union Government is aware of the growing crisis in the quality and availability of generic medicines supplied through Jan Aushadhi Kendras (JAKs) in the country and if so, the details of complaints received and supply gaps identified therein;
(b) the number of cases registered during the last five years against Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) outlets for quality failures, contaminants or substandard formulations, year-wise;
(c) the concrete steps taken to enforce strict quality control, including mandatory batch testing, surprise inspections, blacklisting of non-compliant manufacturers and timelines for recalling substandard medicines supplied under PMBJP;
(d) the measures adopted to strengthen regulatory oversight and transparency in procurement, vendor selection and stocking of generic medicines; and
(e) whether an independent audit mechanism is being created to prevent further lapses, if so, the details thereof?

ANSWER

THE MINISTER OF STATE IN THE MINISTRY OF CHEMICALS AND FERTILIZERS

(SMT. ANUPRIYA PATEL)

(a): Any person may lodge complaint regarding quality and availability of generic medicines supplied through JAKs in the country using the Centralised Public Grievance Redress and Monitoring System (CPGRAMS) portal of the Government of India, or by emailing to complaints@janaushadhi.gov.in, or calling the PMBJP helpline number 1800 180 8080. Although JAKs serve about 15 lakh consumers daily, only 2,102 grievances were lodged in the financial year (FY) 2024-25, constituting less than 0.0004% of consumers transactions. The grievances lodged related primarily to non-availability of specific medicines at particular outlets.

With a view to address any supply gaps and ensure smooth supply and product availability at JAKs, the Pharmaceuticals and Medical Devices Bureau of India (PMBI), which is the implementing agency for PMBJP, has undertaken the following measures:

(i) An end-to-end information-technology-enabled supply chain system has been put in place, consisting currently of five warehouses and 39 distributors across the country.
(ii) Since September 2024, stocking by JAKs of 200 commonly used medicines, consisting of the 100 top-selling medicines in the product basket and 100 fast-selling

medicines in the market, has been incentivised, under which JAK owners are eligible for monthly incentive based on the stocks that they maintain of these medicines.

(iii) In addition, with a view to ensure availability of commonly used products, 400 fast-moving products are monitored regularly by PMBI and demand for the same is forecasted on an ongoing basis. Further, steps have been taken to digitise the forecasting method to augment the procurement process through automation.

(b) and (c): No such cases have been registered against Janaushadhi outlets under PMBJP for quality failures, contaminants or substandard formulations as the action is liable against manufacturers of such medicine. Further, with a view to ensure quality of medicines available at JAKs so that health of patients is not compromised, concrete mechanisms are in place to ensure continuous inspection, testing and standardisation, including the following:

(i) *Supply only from WHO Good Manufacturing Practices (GMP) certified plants:* Only plants that are certified as WHO-GMP compliant by the Central Drugs Standard Control Organisation (CDSCO) after direct inspection are eligible for supply.

(ii) *Distribution only after 100% pre-testing of all medicine batches:* Samples are drawn from 100% of batches supplied at PMBI's warehouses for testing anonymously, and medicines are dispatched for supply to JAKs only after the quality test is passed.

(iii) *Testing only at labs compliant with Good Laboratory Practices (GLP):* Samples are tested only at labs accredited and periodically inspected by the National Accreditation Board for Testing and Calibration Laboratories (NABL) and, in addition, assessed by PMBI for GLP compliance.

On detection of any medicine of Not of Standard Quality (NSQ) category, sale of the said batches of medicines across the entire supply chain is stopped forthwith and such batches available in the supply channel are recalled. Further, in such cases, the tender clauses prescribe appropriate action against the manufacturer, such as forfeiture of security deposit, recovery of cost of entire batch and blacklisting/debarment of manufacturer/drug supplied.

Year-wise details of cases registered against manufacturers who supplies drugs for PMBJP for quality failures are as under:

S. No.	**Financial year**	**Number of batches of products purchased**	**Number of batches reported as NSQ by drug regulatory authorities and cases registered**
1	2020-21	6,955	21
2	2021-22	9,143	29
3	2022-23	12,001	49
4	2023-24	13,000	61
5	2024-25	18,686	46

(d) and (e): With regard to regulatory oversight over drugs in the country, CDSCO and the Ministry of Health and Family Welfare have taken following measures:

(i) In order to assess the regulatory compliance of drug manufacturing premises in the country, CDSCO along with State Drugs Controllers (SDCs) have conducted risk-based inspections of more than 960 premises since December 2022 and based on findings, more than 860 actions such as issuance of show cause notices, stop production order, suspension, cancellation of licenses/product-licenses, warning letters etc., have been taken by the State Licensing Authorities as per the provisions of the Drugs Rules, 1945.

(ii) The Drugs Rules, 1945 have been amended in 2023 to require manufacturers of the top-300 drug formulation brands listed in Schedule H2 to the said rules to print or

affix a bar code or Quick Response (QR) code on the primary packaging label, or on the secondary label where space is insufficient, to store data readable through software applications for authentication. Similarly, the said rules have also been amended to require that every active pharmaceutical ingredient (bulk drug), whether manufactured or imported, shall bear a QR code on each level of packaging containing data readable through software applications to facilitate tracking and tracing.

(iii) As part of quality monitoring, CDSCO uploads details of drug samples that fail quality checks on its website as monthly drug alerts. For samples declared Not of Standard Quality (NSQ) by the drugs testing laboratories under CDSCO, manufacturers are directed to immediately recall the product and stop further distribution. Based on investigation findings, licensing authorities concerned take action under the Drugs and Cosmetics Act, 1940 and the rules made thereunder, including stop-production/testing orders, license suspension or cancellation, warning letters and show cause notices.

(iv) Schedule M to the Drugs Rules, 1945 has been revised *vide* Ministry of Health and Family Welfare's notification dated 28.12.2023, in line with international standards {of the World Health Organization (WHO)}, and the same has come into effect for drug manufacturers with turnover more than ₹250 crore from 29.6.2024. However, for manufacturers having turnover of up to ₹250 crore, the timeline for implementation has been extended till 31.12.2025, *vide* notification dated 11.2.2025.

(v) In February 2024, CDSCO published regulatory guidelines for the sampling of drugs, cosmetics and medical devices by Central and State drugs inspectors. These provide a structured approach to ensure the quality and efficacy of products available in the market through uniform drug sampling methodology.

(vi) An online portal, SUGAM, is in place since September 2023 for integrating the drug testing labs of CDSCO. It automates the entire workflow for testing of medical products (drugs, vaccine, cosmetics and medical devices) to meet quality specifications and trace testing status in laboratories.

(vii) The Drugs Rules, 1945 have been amended to make it mandatory that, in case an applicant intends to market the drug under a brand name or trade name, such applicant shall furnish an undertaking in prescribed form to the licensing authority that such or similar brand name or trade name is not already in existence with respect to any drug in the country and the proposed brand name or trade name shall not lead to any confusion or deception in the market.

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

(ix) Central Government organises residential and regional training and workshops on an ongoing basis to officials of CDSCO and State Drugs Regulatory Authorities on Good Manufacturing Practices. Since April 2023, CDSCO has trained over 43,000 persons.

As regards transparency, it is informed that PMBI selects manufacturers and suppliers through an open tendering process, using the Government's Central Public Procurement Portal, for rate contracts. Further, distributors are appointed based on requirement by inviting expressions of interest (EoI) and following a transparent selection process. Whenever there is requirement, an invitation for EoI or tender is uploaded on the scheme website (www.janaushadhi.gov.in) for authorised distributorship.

With regard to independent measures to prevent lapses, it is stated that independent regulatory oversight as detailed above and testing of samples of medicines supplied to JAKs is done at labs accredited and independently overseen by the National Accreditation Board for Testing and Calibration Laboratories (NABL) serve to safeguard against any lapses.

*****