GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO- 1764
ANSWERED ON- 04/08/2026

QUALITY OF AYUSH DRUGS

1764. SHRI PRAMOD TIWARI

Will the Minister of AYUSH be pleased to state: -

(a) whether batches of Ayush drugs declared "Not of Standard Quality" pointing to presence of heavy metals, mixing of allopathic steroids, pushing unverified efficacy claims etc. have surfaced;

(b) if so, the details thereof;

(c) the details of Pharmacovigilance reports relating to Ayush drugs received during the last three years;

(d) the details of adverse event reports related to Ayush drugs submitted; and

(e) the steps taken/ proposed to be taken to tighten quality control of Ayush drugs?

ANSWER

THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH

(SHRI PRATAPRAO JADHAV)

(a) & (b) The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945, have exclusive regulatory provisions for Ayush drugs. Provisions related to misbranded, adulterated and spurious Ayurveda, Siddha and Unani drugs are prescribed under the Section33E, 33EE and 33EEA respectively and penalty for manufacture for sale or for distribution of any such drugs are prescribed under the section 33-I of Drugs and Cosmetics Act, 1940. Further, Rule 159 of Drugs Rules, 1945 have provisions for cancellation or suspension of licences if the licensee has failed to comply with any of the conditions of the licence or with any provisions of the Drugs and Cosmetics Act, 1940 or the Rules made thereunder.

As prescribed in Drugs and Cosmetics Act, 1940 and Drugs Rules, 1945, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha and Unani drugs, is vested with the State Drug Controllers/State Licensing Authorities appointed by the concerned State/ Union Territory Government. Drug Inspectors collect medicine samples regularly from manufacturing firms or retail shops within their jurisdiction and send them to Drug Testing Laboratory under Drug Control department for quality testing and if any sample is found to be 'Not of Standard Quality', appropriate action is initiated such as preventing the sale of the medicines from the market and appropriate legal actions as per Drugs and Cosmetics Act, 1940 and Rules made thereunder. There are 34 Drug Testing Laboratories available in State/UTs for testing of the Legal Samples drawn by the Drug Inspectors of concerned State/UTs. As per the information received from State/UT Governments, the details of batches of Ayush drugs declared "Not of Standard Quality" due to presence of heavy metals, mixing of allopathic drugs etc. are attached at Annexure-I.

(c) & (d) Ministry of Ayush is implementing a Central Sector Scheme, namely, Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY). The scheme has inter-alia one of the component, "Pharmacovigilance Program for Ayush Drugs" with its major objectives to undertake surveillance of misleading advertisements, enabling timely detection and reporting to the concerned regulatory authorities for appropriate action. The Pharmacovigilance Program for Ayush drugs under AOGUSY scheme functions through a nationwide three-tier network comprising 01 National Pharmacovigilance Co-ordination Centre (NPvCC), 05 Intermediary Pharmacovigilance Centres (IPvCs), and 97 Peripheral Pharmacovigilance Centres (PPvCs) established across the country. The details of adverse event reports relating to Ayush drugs during the last three years are attached Annexure II.

(e) Following steps are taken to strengthen quality control of Ayush drugs-

1) The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 have exclusive regulatory provisions for Ayush drugs. It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units & medicines including proof of safety & effectiveness, compliance with the Good Manufacturing Practices (GMP) as per Schedule T and Schedule M-I of the Drugs Rules, 1945 for Ayurvedic, Siddha, Sowa-rigpa, Unani and Homeopathy drugs respectively and to follow the quality standards of drugs as prescribed in the respective pharmacopoeia. Drug Testing Laboratories are approved by the Ministry of Ayush under Rules 160A to 160J of the Drugs Rules, 1945, for carrying out tests relating to the identity, purity, quality and strength of Ayush drugs. As on date, 118 private Drug Testing Laboratories have been approved by the Ministry across States and Union Territories for conducting such tests in accordance with the provisions of the Drugs Rules, 1945.
2) Drug Inspectors collect medicine samples regularly from manufacturing firms or retail shops within their jurisdiction and send them to Drug Testing Laboratory under Drug Control

department for quality testing and if any sample is found to be 'Not of Standard Quality', appropriate action is initiated such as preventing the sale of the medicines from the market and appropriate legal actions as per Drugs and Cosmetics Act, 1940 and Rules made thereunder.

3) The Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a subordinate organization under Ministry of Ayush, develops pharmacopoeial standards and formulary specifications for Ayush drugs, which serve as the official compendia for determining their identity, purity, and strength. Compliance with these standards is mandatory under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder. PCIM&H also functions as the Appellate Drug Testing Laboratory for Ayush drugs and conducts regular capacity-building programmes for Drug Regulatory Authorities, Drug Analysts, and other stakeholders on standardization, quality control, and testing methodologies to strengthen the quality assurance system for Ayush drugs.
4) Further, Ministry of Ayush is implementing a Central Sector Scheme, namely, Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) to support Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards like WHO-GMP and NABL respectively.
5) In addition, the Ministry of Ayush has undertaken the following initiatives to promote quality assurance and certification of Ayush products:

    i. WHO Certificate of Pharmaceutical Product (WHO-CoPP) to Ayush drugs is issued by Central Drugs Standard Control Organization (CDSCO) after joint inspections of manufacturing units by Drug Inspectors posted in Ayush vertical along with drug inspectors of State/UTs and CDSCO for compliance with WHO Technical Report Series (TRS) guidelines for Herbal Medicines.
    ii. Ministry of Ayush has launched Ayush Quality Mark (AQM) initiative through the Ayush Export Promotion Council (AYUSHEXCIL). Under this framework, the Ayush Quality Mark is being granted after scrutiny and verification of valid quality certifications and statutory approvals issued by the competent Government authorities, such as WHO-GMP, Ayush Premium Mark and other recognised certifications, as applicable.
    iii. Ayush Standard Mark and Ayush Premium Mark are awarded to Ayush Drugs by Quality Council of India (QCI) based on third-party assessment of compliance with prescribed national and international quality standards.

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Annexure-I

As per the information received from State/UT Governments, the details of Ayush drugs declared "Not of Standard Quality" due to presence of heavy metals, mixing of allopathic drugs etc. are as follows:

S. No.	State/UT	Number of Ayush drugs declared "Not of Standard Quality"
1.	Tripura	02 (survey samples)
2.	Uttarakhand	155 (in the last years)
3.	Jharkhand	01
4.	Gujarat	21
5.	Kerala	02
6.	Himachal Pradesh	185
7.	Meghalaya	NIL
8.	Bihar	NIL
9.	Madhya Pradesh	NIL
10.	Puducherry	NIL
11.	Chhattisgarh	NIL
12.	Delhi	NIL
13.	Odisha	NIL
14.	Lakshadweep	NA
15.	Jammu & Kashmir	NIL
16.	Uttar Pradesh	NIL
17.	Goa	NIL
18.	Haryana	NIL
19	Manipur	NIL

Annexure II

The details of the suspected adverse drug event reports related to Ayush drugs during the last three years, are as follows-

Year	Suspected ADR's
2023	420
2024	521
2025	728
Total	**1669**