GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
STARRED QUESTION NO. 337
TO BE ANSWERED ON 24th MARCH 2026

Regulation and standardisation of Ayush medicines

337 # **Shri Rajib Bhattacharjee:**

Will the Minister of ***Ayush*** be pleased to state:

(a) whether Government has taken steps to strengthen quality control and standardisation of Ayush medicines in the States;
(b) if so, the details thereof;
(c) the number of inspections conducted in Ayush medicine manufacturing units during the last three years along with the number of cases in which violations were detected;
(d) whether the Ministry proposes to launch a National Digital Registry for Ayush medicine manufacturers;
(e) if so, the details thereof; and
(f) the steps taken to prevent adulteration or misbranding of herbal medicines in the market?

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH
(SHRI PRATAPRAO JADHAV)

(a) to (f) A statement is laid on the Table of the House.

THE STATEMENT REFERRED TO IN REPLY TO RAJYA SABHA STARRED QUESTION NO 337 for 24th MARCH 2026

(a) and (b) The details of steps taken to strengthen quality control and standardisation of Ayush medicines across the country are as follows: -

1. The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 have exclusive regulatory provisions for Ayurveda, Siddha, Sowa-Rigpa, Unani, and Homoeopathy drugs. Provisions relating to Ayurveda, Siddha, Sowa-Rigpa and Unani Drugs are contained in Chapter IVA and Schedule- I of the Drugs and Cosmetics Act, 1940 and in Rules 151 to 169, Schedules E(I), T & TA of the Drugs Rules, 1945. Further, second schedule (4A) of the Drugs and Cosmetics Act, 1940 provides standards for Homoeopathic drugs and Rules 2dd, 30AA, 67 (C-H), 85 (A to I), 106-A, Schedule K, Schedule M-I of the Drugs Rules, 1945 pertain to Homoeopathic 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 & Schedule M-I of Drugs Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.
2. Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a subordinate office under Ministry of Ayush lays down the formulary specifications and pharmacopoeial standards for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs, which serves as official compendia for ascertaining the quality (identity, purity and strength) of the ASU&H drugs and compliance to this quality standards are mandatory for the manufacturing for sale of ASU&H drugs across the country. So far, 2325 quality standards on raw materials (single drugs of plant/ animal/ mineral/ metal/ chemical origin) used in ASU&H drugs, 426 quality standards of ASU formulations and 2799 formulary specifications of ASU drugs has been published. In addition to above, supporting documents in the form of Macro, Microscopic & TLC Atlas on 392 single drugs incorporated in Ayurvedic Pharmacopoeia of India (API) has also published. Further, PCIM&H also acts as the Central Drugs Laboratory for Indian Medicine and Homoeopathy for the purpose of testing or analysis of ASU&H Drugs.
3. Rule 160 A to J of the Drugs Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratory for carrying out such tests of identity, purity, quality and strength of Ayurveda, Siddha, Sowa-Rigpa and Unani drugs and raw materials used in their manufacture on behalf of licensee for manufacture for sale of Ayurveda, Siddha, Sowa-Rigpa and Unani drugs. As on date, 108 private laboratories are approved or licensed under the provisions of Drugs Rules, 1945. Further, there are 34 Drug Testing Laboratories of State/UTs for testing quality of Ayurveda, Siddha, Sowa-Rigpa and Unani drugs and raw materials including legal samples.
4. As prescribed in Drugs and Cosmetics Act, 1940 and Rules made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs, is vested with the State/UT Drug Controllers/ Licensing Authorities appointed by the concerned State/ UT Government.

5. Drug Inspectors collect medicine samples regularly from manufacturing firms or sale 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 drugs from the market and appropriate legal actions as per Drugs and Cosmetics Act, 1940 and Rules made thereunder.
6. Ministry of Ayush has established an Ayush vertical in the Central Drugs Standard Control Organisation (CDSCO), which includes the posts of 1 Deputy Drugs Controller, 4 Assistant Drugs Controllers, and 4 Drug Inspectors. Drug Inspectors posted in Ayush vertical, inspect various manufacturing units including risk-based inspections in coordination with the licensing authorities/drug inspectors of the respective States/UTs for ensuring safety and quality of Ayush medicines.

(c) As per the information received from states/UTs governments, the details of the number of inspections conducted of Ayush Medicine manufacturing units during the last three years along with the number of cases in which violations were detected are attached at **Annexure-I.**

(d) and (e) Ministry of Ayush has launched e-Aushadhi portal to facilitate an online system for granting manufacturing license, including submission of applications and grant of product approvals. The initiative aims to enhance transparency, improve efficiency, and ensure uniformity in the implementation of regulatory provisions across the sector. Further, training programmes have been conducted for Licensing Authorities and drug manufacturers to familiarize them with the functionalities of e-Aushadhi portal and to ensure its effective adoption.

(f) Section 33EEB of Drugs and Cosmetics Act, 1940 prohibits manufacturing for sale of Ayurvedic, Siddha and Unani (ASU) drugs, which are not in accordance with standards, prescribed in relation to that drug by Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H). Section 33EE of the Drugs and Cosmetics Act, 1940 defines adulterated ASU drugs and Section 33EEC of the Drugs and Cosmetics Act, 1940 prohibits the manufacturing for sale of any adulterated ASU drugs. Further, the penalties for manufacturing for sale of adulterated ASU drugs are provided under Section 33-I of Drugs and Cosmetics Act, 1940.

Ministry of Ayush is implementing a Pharmacovigilance Program for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs under its Central Sector Scheme-Ayush Oushadhi Gunvatta evam Uttpadan Samvardhan Yojana (AOGUSY). The program operates through a dedicated three-tire network comprising one National Pharmacovigilance Co-ordination Centre (NPvCC), five Intermediary Pharmacovigilance Centres (IPvC) and ninety-seven Peripheral Pharmacovigilance Centres (PPvC) across the country. The All India Institute of Ayurveda (AIIA), New Delhi under Ministry of Ayush serve as the NPvCC for the implementation of the program. All PPvCs routinely report Misleading Advertisements (MLAs)/Objectionable Advertisements (OAs) and suspected Adverse Drug Reactions (ADRs) to the respective State/UT Licensing Authorities for necessary action.

Further, to strengthen the pharmacovigilance program for Ayush drugs, Ministry of Ayush has launched an IT enabled online portal “Ayush Suraksha” on 30th May 2025 to capture MLAs/OAs and report ADRs related to the Ayush medicine.

The portal features a centralized dashboard for real-time tracking of suspected ADRs and capturing of MLAs /OAs for prompt regulatory action and comprehensive data analysis. The portal is aligned with the National Pharmacovigilance Program and integrates data from three tier Pharmacovigilance Centres and forwards complaints to the concerned authorities, including State/UT Licensing Authorities (Ayush) and Central Govt. bodies such as Ministry of Information and Broadcasting (MoIB), Central Consumer Protection Authority (CCPA), National Commission for Indian System of Medicine (NCISM), National Commission for Homoeopathy (NCH), Press Council of India (PCI), Food Safety and Standards Authority of India (FSSAI) for its resolution.

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Annexure-I

State/UT wise details of number of inspections conducted of Ayush Medicine manufacturing units during the last three years along with the number of cases in which violations were detected are as follows: -

S. No.	State/UT	Year	Number of inspections conducted of Ayush manufacturing units during the last three years.	Number of cases in which violations were detected.
1.	Hayana	2023-2025	330	15
2	Odisha	2023-24	08	00
		2024-25	12	01
		2025-26	08	00
3	Tamil Nadu	2023	442	33
		2024	513	08
		2025	643	35
4	Kerala	2023	372	00
		2024	314	00
		2025	342	00
5	Maharashtra	2023-24	371	08
		2024-25	384	30
		2025-26	140	14
6	Madhya Pradesh	2023	111	04
		2024	127	04
		2025	116	61
7	Delhi	2022-23	211	03
		2023-24	207	03
		2024-25	201	01
8	Bihar	2023-2025	61	11
9	Uttarakhand	2023-2025	100	10
10	Punjab	2023	242	00
		2024	240	00
		2025	272	00
11	Gujarat	2023	172	05
		2024	194	25
		2025	91	19
12	Tripura	There is no manufacturing unit in Tripura.		