GOVERNMENT OF INDIA
MINISTRY OF AYUSH
LOK SABHA

UNSTARRED QUESTION NO. 1010
TO BE ANSWERED ON 05th DECEMBER, 2025

Quality AYUSH Medicines and Products

1010. Shri Janardan Singh Sigriwal:

Will the Minister of AYUSH

be pleased to state:

(a) whether any shortfall has been noticed in manufacturing of various AYUSH medicines and if so, the details thereof;
(b) whether the Government proposes to formulate any mechanism to address the issue of standardization and quality control of AYUSH medicines and products in the country;
(c) if so, the details thereof along with the efforts to improve the quality of AYUSH medicines/products, State/UT-wise, particularly in Bihar;
(d) the measures taken/proposed to be taken to enhance research and development in the field of AYUSH along with the efforts to collaborate with international organizations; and
(e) the plans of the Government to promote quality AYUSH medicines and products for wider use by the consumers?

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

(a) As per the information received from States/ UTs governments, there is no shortfall noticed in the manufacturing of various Ayush medicines**.**

(b) and (c) The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 have exclusive regulatory provisions for Ayurvedic, Siddha, Sowa Rigpa, Unani, and Homoeopathy drugs. Provisions related to Ayurveda, Siddha, Sowa Rigpa and Unani Drugs are contained in Chapter IVA and Schedule- I of the Drugs and Cosmetics Act, 1940 and 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 of Good Manufacturing Practices (GMP) including proof of safety & effectiveness as per Schedule T & Schedule M-I of Drugs Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

Ministry of Ayush, Government of India has established Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) as its subordinate office. PCIM&H 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. As per the Drugs & Cosmetics Act, 1940 and rules thereunder, the compliance to these quality standards are mandatory for the production of ASU&H drugs being manufactured in India. So far, 2269 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 & Thin-layer chromatography (TLC) Atlas on 392 single drugs incorporated in Ayurvedic Pharmacopoeia of India (API) has also been published.

PCIM&H also acts as the Appellate Drugs testing Laboratory for testing or analysis of ASU&H Drugs. In addition, it conducts capacity-building trainings at regular intervals for the standardization, quality control, and testing or analysis of ASU&H drugs for Drug Regulatory Authorities, Drug Analysts, and other relevant stakeholders, with a focus on laboratory techniques and methodologies essential for ensuring the quality of ASU&H drugs.

Rule 160 A to J of the Drugs Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratory for carrying out tests of identity, purity, quality and strength of Ayurvedic, Siddha, Sowa Rigpa and Unani drugs as may be required under the provisions of these rules. As on date, 34 State/UTs Drug Testing Laboratories and 108 private laboratories are approved or licensed under the provisions of Drugs Rules, 1945 for quality testing of Ayurvedic, Siddha, Sowa Rigpa and Unani drugs and raw materials.

As per the information received from states/UTs Governments including Bihar, the details of the mechanism to address the issue of standardization and quality control of Ayush medicines and products in the country along with the efforts to improve the quality of Ayush medicines/products are attached at Annexure**.**

(d) Ministry of Ayush has established Central Councils for Research in Ayurveda, Yoga & Naturopathy, Unani, Siddha & Homoeopathy as apex organizations for undertaking, coordinating, formulating, developing and promoting research in Ayush systems on scientific lines. Core Research activities comprise of Medicinal Plant Research (Medico-Ethno Botanical Survey, Pharmacognosy and in vitro-propagation technique), Drug Standardization, Pharmacological Research, Clinical Research, Literary Research & Documentation and Tribal Health Care Research Programme. Research activities are carried out through its peripheral Institutes/Units located across the country and in collaboration with various Universities, Hospitals and Institutes.

Further, the Ministry of Ayush is implementing the Central Sector Scheme namely AYURGYAN Scheme from FY 2021-22. The Scheme has 03 components viz. (i) Capacity Building & Continuing Medical Education (CME) in Ayush (ii) Research & Innovation in Ayush from the FY 2021-22 and iii) Ayurveda Biology Integrated Health Research is also added under the scheme from FY 2023-24. Under the Research & Innovation in Ayush and Ayurveda Biology Integrated Health Research component, financial assistance is being

provided to the Organizations/Institutions for research studies, for promotion of research in Ayush system.

The Ministry of Ayush is implementing the central sector scheme for Promotion of International Cooperation for Ayush (IC Scheme). Under this scheme, Ministry provides support to Indian Ayush drug Manufacturers/ Ayush Service providers to give boost to the export of Ayush products and services, facilitates the International promotion, development and recognition of Ayush systems of medicine, foster interaction of stakeholders and market development of Ayush at international level, promote academics and research through the establishment of Ayush Academic Chairs in foreign countries and holding training workshop/symposiums for promoting and strengthening awareness and interest about Ayush Systems of Medicine at international level.

Under this IC Scheme, 25 Country-to-Country MoUs, 15 Ayush Chair MoUs and 52 Institute-to-Institute level MoUs have been signed.

(e) Ministry of Ayush has implemented Central Sector Scheme Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY). The total financial allocation to this scheme is Rs. 122.00 crores for five years. The components of AOGUSY scheme are as follows -

A. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.

B. Pharmacovigilance of ASU&H drugs including surveillance of misleading advertisements.

C. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.

D. Support for development of standards and accreditation/certification of Ayush products & materials in collaboration with Bureau of Indian Standards (BIS), Quality Control of India (QCI) and other relevant scientific institutions and industrial R&D centres. Detailed guidelines of AOGUSY scheme are available at **https://ayush.gov.in/images/Schemes/aoushdhi.pdf**.

Further Ministry of Ayush encourages following certifications of Ayush products as per details below: -

• The scheme for Certification of Pharmaceutical Product (CoPP) as per World Health Organization (WHO) guidelines is extended to Ayurvedic, Siddha and Unani (ASU) medicines. This scheme is administered by Central Drugs Standard Control Organization (CDSCO) and the certificate is granted on the basis of joint inspection of the applicant manufacturing unit by the representatives of CDSCO, Ministry of Ayush and the concerned State Licensing Authority.

• Quality Certifications Scheme is implemented by the Quality Council of India (QCI) for grant of Ayush mark viz. Ayush standard and Ayush premium marks to Ayurvedic, Siddha and Unani products on the basis of third party evaluation of quality in accordance with the status of compliance to GMP and WHO-GMP standards, respectively.

****

Annexure

As per the information received from states/UTs Governments including Bihar, the details of the mechanism to address the issue of standardization and quality control of Ayush medicines and products in the country along with the efforts to improve the quality of Ayush medicines/products are as follows:

S. No.	Name of the State/ UT	Details
1.	Uttarakhand	State government nominated 14 Drug Inspectors in the State to check the quality and production of Ayurvedic & Unani medicines. There are 07 Drug testing laboratories (DTLs) are working in Uttarakhand in which 01 Government and 06 drug testing laboratories are approved by Ministry of Ayush in Private sector are sanctioned under Drug & Cosmetic Act 1940, Ruls1945 under rule 160A to 160J, for checking the quality of Ayurvedic & Unani medicines. Uttarakhand Ayurvedic University nominated as peripheral pharmacovigilance Centre for compiling and reporting of adverse drug reaction (ADR). All manufacturing Units are GMP certified, the respective District's Drug Inspectors regularly do inspection, and Sampling for testing.
2.	Madhya Pradesh	Madhya Pradesh have 01 state DTL and 07 Private DTLs for testing of Ayush medicine. In addition, 51 Drug Inspectors are notified in state for Ayush medicine. In addition 07 pharmacovigilance centers are working as monitoring system.
3.	Delhi	Routine inspections and lifting of survey samples are undertaken as part of regular enforcement activities to improve the quality of Ayush medicines/products.
4.	Puducherry	ISM Expert Committee is Constituted in UT of Puducherry. Products were verified, evaluated and approved by ISM Expert Committee. Based on the recommendations from ISM Expert Committee, necessary product approval is issued. Product approvals are issued as per the rules 158(B) (II) A read with Chapter IVA of Drugs and Cosmetics Act 1940 & Rules 1945. Regular monitoring and Inspection is carried out by the Drugs Inspectors, Department of Drugs Control, Puducherry.

5.	Ladakh	In UT Ladakh the Sowa Rigpa medicine suppliers are directed to ensure date of manufacturing and date of expiry on label.
6.	Kerala	The Government of Kerala has constituted an expert committee for the standardization of Ayurveda, Siddha, Unani Drugs. The committee had submitted a comprehensive draft report with recommendation for implementation of various steps to improve the quality of Ayurveda, Siddha, Unani Drugs.
7.	Tripura	A State DTL has been established to test Ayush drugs for quality, purity, and strength. A central sector scheme (AOGUSY) implemented to provide financial assistance to drug testing laboratory to achieve higher standards. Drug inspectors conduct regular inspections of the market and draw samples for quality checking
8.	Haryana	A State Ayurvedic Drug Testing Laboratory is functional in Haryana State. Moreover, 12 Private Drug Testing Laboratories are also granted licence for testing of ASU drugs/medicines under rule 160 B of Drug and Cosmetic Rules-1945.
9.	Arunachal Pradesh	State Drug Testing Laboratory (Ayush) and Govt. Ayurvedic Pharmacy are established in Arunachal Pradesh for quality control of Ayush Drugs.
10.	Uttar Pradesh	For testing/analysis, the State Government operates 01 Drug Testing Laboratory with 01 State Government Analyst, Ayurveda & Unani Medicine, Uttar Pradesh, and 04 Private Drug Testing Laboratories certified by the State Government under rule 160 A to J of the Drug and Cosmetics Act- 1945. One Pharmacovigilance Centre situated at Central Research Institute of Unani Medicine, Lucknow, Uttar Pradesh and 60 Drug Inspector Appoint in Uttar Pradesh Including Ayurveda and Unani Department.
11.	Bihar	The Drugs Control Administration, Department of Health, Bihar continuously monitor the Quality of drugs (Ayush) by performing sampling & testing of the marketed drugs in the state through its inspectorate staff. State Govt. has also notified government Analyst and Drugs Testing Laboratory, Agamkuan, Patna for the test and Analysis of Ayurvedic, Unani and Homoeopathic Medicines.
12.	Odisha	One State Drugs Testing and Research Laboratory (ISM), Bhubaneswar is functioning in the State to address the issue of standardisation and quality control

		of AYUSH medicines and products in the State.
13.	Maharashtra	Nil
14.	Lakshadweep	Nil
15.	Gujrat	Nil
16.	West Bengal	Nil