GOVERNMENT OF INDIA
MINISTRY OF AYUSH
RAJYA SABHA
UNSTARRED QUESTION NO. 962
TO BE ANSWERED ON 29th July, 2025

"Standardization and quality control of Ayush medicines in the country"

962. Shri R. Dharmar:

Will the Minister of AYUSH be pleased to state:

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

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

(SHRI PRATAPRAO JADHAV)

(a) and (b) The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 have exclusive regulatory provisions for Ayurvedic, Siddha, Sowa-Rigpa, Unani, and Homoeopathy 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), 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 under Schedule II of Drugs & Cosmetics Act, 1940. Details of quality standards and formulary specifications are available at **Annexure-I.**

3. 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. Further, it imparts Capacity Building Trainings at regular interval for standardization/quality control/ testing or analysis of ASU&H drugs to Drug Regulatory Authorities, State Drug Testing Laboratories (Drug Analyst) and other stakeholders on quality control of ASU&H drugs on laboratory techniques and methods used to maintain the quality of ASU&H drugs.

4. Drug Testing Laboratories are being recognised under Rule 160 A to J of the Drugs Rules, 1945 for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs. As on date, 108 private laboratories are approved or licensed under the provisions of Drugs Rules, 1945 for manufacturers. 34 Drug Testing Laboratories of State/UTs are testing quality of Ayurvedic, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs and raw materials for legal samples.

(c) Government of India has established Central Council for Research in Ayurvedic Sciences, Central Council for Research in Unani Medicine, Central Council for Research in Homoeopathy, Central Council for Research in Siddha and Central Council for Research in Yoga & Naturopathy under the Ministry of Ayush as apex organizations for undertaking,

coordinating, formulating, developing and promoting research in Ayush system on scientific lines. Core Research activities comprise of Medicinal Plant Research (Medico-Ethno Botanical Survey, Pharmacognosy and cultivation), 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 also in collaboration with various Universities, Hospitals and Institutes.

2. Further, 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 this FY 2023-24.Under the Research & Innovation in Ayush and Ayurveda Biology Integrated Health Research component, financial assistance is provided to the Organizations/Institutions for research studies, for promotion of research in Ayush system.

3.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 including Ayurveda. Under this Scheme 25 Country to Country MoUs, 15 Ayush Chair MoUs and 52 Institute to Institute level MoUs have been signed.

(d) Ministry of Ayush has implemented Central Sector Scheme Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) to support Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards under one of the components. The total financial allocation to this scheme is Rs. 122.00 crores for five years.

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

- An Ayush vertical has been created in Central Drugs Standard Control Organization (CDSCO) to strengthen regulatory measures ensuring safety and quality of Ayush drugs. Further, CDSCO issues WHO Certificate of Pharmaceutical Product (WHO-CoPP) to Ayush drugs having compliance to such standards.

- Quality Certifications Scheme implemented by the Quality Council of India (QCI) for grant of AYUSH standard and premium mark to Ayurvedic, Siddha and Unani products on the basis of third-party evaluation of quality in accordance with the status of compliance to domestic and international standards.

(e) As per the information received from States/ UTs governments, details of shortfall noticed in the manufacturing of various Ayush medicines are available at **Annexure-II.**

****

Annexure-I

Details of quality standards on raw materials used in ASU&H drugs, quality standards of ASU formulations, formulary specifications of ASU drugs and Macro-Microscopic & TLC Atlas on single drugs incorporated in Ayurvedic Pharmacopoeia of India (API) are as follows-

Name of Pharmacopoeia	Published quality standards of single drugs
Ayurvedic Pharmacopoeia of India (Part I, Vol. I to X)	665
Siddha Pharmacopoeia of India (Part I, Vol. I to II)	139
Unani Pharmacopoeia of India (Part I, Vol. I to VII)	338
Homoeopathic Pharmacopoeia of India (Vol. I to XI)	1127

Name of Pharmacopoeia	Published quality standards of formulations
Ayurvedic Pharmacopoeia of India (Part II, Vol. I to V)	223 and 01 standalone quality standard.
Siddha Pharmacopoeia of India (Part II)	01 standalone quality standard.
Unani Pharmacopoeia of India (Part II, Vol. I to IV)	200 and 01 standalone quality standard.

Formulary	Specification
Ayurvedic Formulary of India	1035 (Part I to IV) and 01 standalone formulary specification.
Siddha Formulary of India	532 (Part I to II) and 01 standalone formulary specification.
National Formulary of Unani Medicine	1229 (Part I to VI) and 01 standalone formulary specification.

Annexure-II

State/ UT-wise details of shortfall noticed in the manufacturing of various Ayush medicines are as follows -

<table>
<tr><th>S.no.</th><th>Name of the State/ UT</th><th>Details of shortfall noticed</th></tr>
<tr><td>1.</td><td>Tripura</td><td>
<table>
<tr><th>Year</th><th>Misbranded</th><th>Not of standard</th></tr>
<tr><td>2024-2025</td><td>36</td><td>-</td></tr>
<tr><td>2023-2024</td><td>07</td><td>-</td></tr>
<tr><td>2022-2023</td><td>62</td><td>03</td></tr>
<tr><td>2021-2022</td><td>-</td><td>-</td></tr>
<tr><td>2020-2021</td><td>4</td><td>-</td></tr>
</table>
</td></tr>
<tr><td>2.</td><td>Jharkhand</td><td>Complaint cases have been registered, and action has been initiated against firm found involved in substandard products, adulterated, spurious drugs or violations of the Drugs and Cosmetics Act, 1940 and Rules, 1945.
Additionally, regulatory actions such as suspension and cancellation of licences and product approvals have been initiated against manufacturers found involved in misleading claims and other violations of the Drugs and Cosmetics Act, 1940 and Rules, 1945.</td></tr>
<tr><td>3.</td><td>Ladakh</td><td>At present there is no standardization of formulation and packaging of Sowa-Rigpa medicines in the country.</td></tr>
<tr><td>4.</td><td>Delhi</td><td>All the manufacturing units are in the state of Delhi are complying GMP norms as per the provisions of the Drugs and Cosmetics Act, 1940.</td></tr>
<tr><td>5.</td><td>Maharashtra</td><td>NIL</td></tr>
<tr><td>6.</td><td>Puducherry</td><td>NIL</td></tr>
<tr><td>7.</td><td>Uttarakhand</td><td>NIL</td></tr>
<tr><td>8.</td><td>Goa</td><td>NIL</td></tr>
<tr><td>9.</td><td>Assam</td><td>NIL</td></tr>
<tr><td>10.</td><td>Mizoram</td><td>NIL</td></tr>
<tr><td>11.</td><td>Kerala</td><td>NIL</td></tr>
<tr><td>12.</td><td>Karnataka</td><td>NIL</td></tr>
<tr><td>13.</td><td>Odisha</td><td>NIL</td></tr>
</table>

14.	Manipur	NIL
15.	Haryana	NIL
16.	Gujarat	NIL
17.	Lakshadweep	NIL
18.	Arunachal Pradesh	NIL

****