

**GOVERNMENT OF INDIA  
MINISTRY OF AYUSH**

**RAJYA SABHA  
UNSTARRED QUESTION NO. 819  
TO BE ANSWERED ON 11<sup>th</sup> FEBRUARY, 2025**

**“National regulatory framework for AYUSH”**

**819.** Shri Narhari Amin:

Shri Jaggesh:

Will the Minister of Ayush be pleased to state:

- (a) the manner in which a national regulatory framework would ensure the standardization of AYUSH medicines and practices across the country;
- (b) the manner in which the framework plans to support research and innovation in AYUSH, particularly in integrating traditional practice with modern science;
- (c) the initiatives taken to educate the public and healthcare professionals about the benefits and limitations of AYUSH systems; and
- (d) the proposed timeline for implementing the framework?

**ANSWER**

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

**(a)&(d)** Ministry of Ayush is ensuring the standardization of Ayush medicines and practices across the country as below:

1. As prescribed in the Drugs and Cosmetics Act, 1940 and Rules made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurvedic, Siddha, Unani and Homoeopathic (ASU&H) drugs is vested with the State Drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government.
2. Rule 158B of the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurveda, Siddha and Unani (ASU) drugs and Rule 85 A to I of the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathic medicines. It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units and 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 and quality standards of drugs given in the respective pharmacopoeia. Rule 159 of the Drugs Rules, 1945 has provisions for cancellation or suspension of licenses if the licensee has failed to comply with any of the conditions of the license or with any provisions of the Drugs and Cosmetics Act, 1940 and Rules made thereunder.

3. Rule 160A 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 ASU drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of ASU drugs. As on date, 34 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 106 laboratories are approved or licensed under the provisions of the Drugs and Cosmetics Act, 1940 & Rules made thereunder for quality testing of ASU drugs and raw materials.

4. Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) on behalf of Ministry of Ayush lays down the Formulary specifications and Pharmacopoeial Standards for ASU&H drugs, which serve as official compendia for ascertaining the Quality Control (identity, purity and strength) of ASU&H drugs, included herein, as per the Drugs & Cosmetics Act, 1940 and Rules 1945, thereunder and compliance to these quality standards are mandatory for ASU&H drugs being manufactured in India. Implementation of these Pharmacopoeial standards ensures that the medicines reaching to masses conform to optimum quality standards in terms of identity, purity and strength. Pharmacopoeias describe the minimum standards/ specification to which a pharmaceutical product should comply with. This includes standards for raw materials for identity, purity, strength and quality to develop and standardize method of preparation, dosage forms, etc. PCIM&H act as an appellate drug testing laboratory to receive the samples from Government agencies as per the Drugs & Cosmetics Act, 1940 & Rules 1945 thereunder for ascertaining their quality. Further, PCIM&H on behalf of Ministry of Ayush also imparts mini training to the Drug Regulatory Authorities, State Drug Testing Laboratories (Drug Analysts) etc. on laboratory techniques and methods used to maintain the quality of ASU&H drugs.

5. Pharmacovigilance Centres for ASU&H drugs set up in different parts of the country under the Central Scheme of Ministry of Ayush are mandated to monitor and report the misleading advertisements to the respective State Regulatory Authorities. A three tier structure comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs) is established. All India Institute of Ayurveda (AIIA), New Delhi under Ministry of Ayush is the National Pharmacovigilance Co-ordination Centre (NPvCC) for the implementation of the National Pharmacovigilance program for ASU&H drugs. Objectionable advertisements are being reported to the respective State Licensing Authorities by PPvC at regular intervals.

6. Central Sector Scheme for Ayush Oushadhi Gunavatta evam Utpadan Samvardhan Yojana (AOGUSY) has been implemented for the year 2021-2026. The components of the AOGUSY Scheme are as under:

- 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 and materials in collaboration with Bureau of Indian Standards (BIS), Quality Control of

India (QCI) and other relevant scientific institutions and industrial research and development centres.

(b) Ministry of Ayush is implementing the Central Sector Scheme namely AYURGYAN having 03 components viz. (i) Capacity Building & Continuing Medical Education (CME) in Ayush (ii) Research & Innovation in Ayush (Erstwhile EMR Scheme) since 2021-22 and (iii) Ayurveda Biology Integrated Health Research (ABIHR) added since 2023-24, with the aim to support Education, Research & Innovation in Ayush by providing academic activities, training, capacity building, research and development activities in the field of Ayush.

Ministry of Ayush has also implemented Central Sector Scheme namely AYURSWASTHYA YOJANA since 2021-22. The Scheme has 02 components viz. (i) Ayush and Public Health Initiative (PHI) and (ii) Upgradation of facilities to the Centre of Excellence. Under Centre of Excellence, financial assistance is provided to support creative and innovative proposals of prestigious organizations with well-established buildings and infrastructure and wish to work for Ayush systems to the level of Centre of Excellence. 09 organizations of National repute have been funded under Centre of Excellence component to integrate the knowledge of Ayurveda with the modern system of medicine. Details are provided in Annexure I.

Government of India has established Central Council for Research in Ayurvedic Sciences (CCRAS), Central Council for Research in Unani Medicine (CCRUM), Central Council for Research in Homoeopathy (CCRH), Central Council for Research in Siddha (CCRS) and Central Council for Research in Yoga & Naturopathy (CCRYN) 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 in-vitro propagation techniques, Drug Standardization, Pharmacological Research, Clinical Research, Literary Research and 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. The research outcomes of the clinical trials are being published in peer reviewed journals.

(c) Ministry of Ayush has taken following initiatives to educate the public and healthcare professionals about the benefits and limitations of Ayush system:

1. The Ministry has implemented the Central Sector Scheme for Promotion of Information, Education and Communication (IEC) in Ayush to create awareness regarding Ayush Systems of Medicine. This aims to reach out to all sections of the population across the country. This scheme provides assistance for organizing National/State Arogya Fairs, Yoga Fests/Utsavs, Ayurveda Parvs, etc. The Ministry also undertakes Multi-Media and Print Media Campaigns for creating awareness about Ayush Systems.

2. 12 National Institutes and 05 Research Councils under the aegis of Ministry of Ayush are engaged in Outpatient & Indoor patient services and provide management of various ailments through Ayush system of medicines. Details of these National Institutes and Research

Councils are available at <https://www.ayush.gov.in>. These Institutes/ Councils organize Arogya Melas, Awareness Camps, Treatment Camps, Radio & TV talks, Outreach programs like Swasthya Rakshan Program (SRP), Schedule Caste Sub Plan (SCSP) Research Program and Tribal Health Care Research Program (THCRP) for creating awareness on Ayush systems of healthcare among the general public. Central Council for Research in Ayurvedic Sciences (CCRAS) has three journals named Journal of Drug Research in Ayurvedic Sciences (JDRAS), Journal of Research in Ayurvedic Sciences (JRAS) and Journal of Indian Medical Heritage (JIMH) which are also available electronically in the public domain free of cost to enable dissemination of the outcomes of research among the public. So far, the Council has published about 409 books, monographs, and technical reports and they are being sold or distributed to disseminate research outcomes and merits of Ayurveda at large.

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**ANNEXURE-I**

Details of 09 organizations of National repute funded under Centre of Excellence component to integrate knowledge of Ayurveda with modern system of medicine under AYURSWASTHYA Scheme:

(Amount in Cr.)

S. No.	Name of the Organization	State	Project Name	Fund Released			
				2021-22	2022-23	2023-24	2024-25
1.	Tata Memorial Centre, (TMC) Mumbai	Maharashtra	Centre of Excellence for Discovery and Development of AYUSH Medicine for Cancer Care	-	-	2.00	1.62
2.	Central Drug Research Institute (CDRI), Lucknow	Uttar Pradesh	Center of Excellence for Fundamental and Translation Research in Ayurveda at Central Drug Research Institute	-	-	2.00	1.99
3.	Jawaharlal Nehru University, (JNU) New Delhi	Delhi	Functional-based Centre of Excellence on Ayurveda and Systems Medicine	-	-	1.01	2.44
4.	Indian Institute of Technology (IIT) Delhi	Delhi	Centre of Excellence in Sustainable Ayush for Advanced technological solutions, startup support and net zero sustainable solutions for Rasasauhies	-	-	2.00	1.14
5.	Indian Institute of Science (IISC) Bengaluru	Karnataka	Centre of Excellence in Diabetes and Metabolic Disorders	-	-	2.00	1.82
6.	Centre for Integrative Medicine and Research (CIMR), AIIMS New Delhi	Delhi	Centre of Excellence for Yoga & Ayurveda	-	2.05	2.04	-
7.	National Institute of Mental Health and Neurosciences (NIMHANS), Bangalore	Karnataka	Centre of Excellence in Ayush Research	-	0.85	0.37	-
8.	Institute of Liver and Biliary Sciences (ILBS)	Delhi	Effects of Indian Foods and Ayurvedic drugs on healthy and Liver diseases	3.97	2.61	-	-
9.	Indian Institute of Technology, (IIT) Jodhpur	Rajasthan	Centre of Excellence in AYURTech for Integrative Precision Health and Medicine	4.00	-	4.00	-