

AYUSH



# Government Strengthens Qualitative Production and Distribution of Ayush Medicines through Comprehensive Regulatory and Certification Initiatives

## Ministry of Ayush Advances Scientific Research through AYURGYAN Scheme and Apex Research Councils

## Ministry of Ayush Enhances Global and National Outreach through Information Education and Communication (IEC) Campaigns, Research Initiatives, and International Collaborations

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The Government has taken following steps for the qualitative production and distribution of Ayush medicines:

1. The Drugs and Cosmetics Act, 1940 & rules made thereunder have exclusive regulatory provisions regarding manufacture for sale or for distribution of 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. Rule 160 A to J of the Drugs Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratories for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurvedic, Siddha and Unani drugs.
3. Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) on behalf of Ministry of Ayush lays down the Formulary specifications and Pharmacopoeial Standards for Ayurveda, Siddha, Unani and Homoeopathic drugs, which serves as an official compendia for ascertaining the Quality Control (identity, purity and strength) of Ayush drugs, as per the Drugs &

Cosmetics Act, 1940 & rules made thereunder. Compliance to these quality standards are mandatory for Ayush drugs being manufactured in India.

4. Pharmacovigilance Centres for Ayurveda, Siddha, Unani and Homoeopathic drugs set up in different parts of the country under the Central Sector Scheme of Ministry of Ayush are mandated to report adverse drug reactions to the respective State Regulatory Authorities.
5. Central Sector Scheme, Ayush Oushadhi Gunavatta evam Utpadan Samvardhan Yojana (AOGUSY) has been implemented for the year 2021-2026. One of the components of this Scheme is to strengthen and up-grade Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.
6. 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.
7. Quality Certifications Scheme implemented by the Quality Council of India (QCI) for grant of Ayush 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.

Further, Government has taken following steps for widening and deepening research in Ayush medicines:

1. 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 and (iii) Ayurveda Biology Integrated Health Research added under the scheme from FY 2023-24. Under the Research & Innovation in Ayush component, financial assistance is provided to the eligible Organizations/Institutions across the country as per the provision contained in the scheme guidelines to support clinical, fundamental, pharmaceutical, literary and medicinal plant research in Extra Mural mode.
2. 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.

Ministry of Ayush has implemented 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, Print Media Campaigns for creating awareness about Ayush systems.

CCRAS, CCRUM, CCRH, CCRS and CCRYN are the apex organizations established under the Ministry of Ayush for undertaking, coordinating, formulating, developing and promoting research in Ayush system on scientific lines. The Councils are also engaged in awareness activities for the promotion of Ayush systems through IEC activities and through electronic and print media for common people in English, Hindi, and regional languages, which are widely distributed through National/ State level Arogya health melas, health camps, exhibitions, expos and outreach programs.

Ministry of Ayush has taken initiative for inclusion of 'Traditional Medicine' chapter in the International Classification of Disease (ICD-10 and 11) supporting the scientific research, Ayush Export Promotion Council (AYUSHEXCIL), WHO Global Traditional Medicine Centre (GTMC) and celebration of Yoga and Ayurveda day etc. worldwide.

In addition, the Ministry of Ayush has taken the following steps towards international promotion, development and recognition for Ayush systems of medicine:

1. Signed 25 Country to Country MoUs for Co-operation in field of Traditional Medicine and Homoeopathy with foreign nations.
2. Signed 15 MoUs with International Institutes for setting up of Ayush Academic Chairs in foreign nations.
3. 51 Institute to Institute level MoUs with foreign institutes for undertaking Collaborative Research/Academic collaboration.
4. Supported the establishment of 43 Ayush Information Cells in 39 foreign nations.
5. Offering scholarships to foreign nationals for studying Ayush courses in recognized Ayush institutions in India under International Fellowship/Scholarship Programs.

This information was given by Union Minister of State (I/C) of the Ministry of Ayush, Shri Prataprao Jadhav in a written reply in Rajya Sabha today.

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**MV/AKS/SG**

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