GOVERNMENT OF INDIA

MINISTRY OF AYUSH

LOK SABHA

UNSTARRED QUESTION NO. 3425

TO BE ANSWERED ON 08th AUGUST 2025

"Development and Regulation of AYUSH Medicines"

3425. Shri Anup Sanjay Dhotre:

Will the Minister of Ayush be pleased to state:

(a) whether any mechanisms are put in place to ensure safety, efficacy and quality control of AYUSH formulations and if so, the details thereof;

(b) whether any National AYUSH Pharmacopoeia or Certification Body has been developed for this purpose and if so, the details thereof;

(c) whether the Government is encouraging research and evidence generation for AYUSH-based therapies;

(d) if so, the details thereof;

(e) the current status of the Ayush Grid for data collection on traditional medicines; and

(f) whether the Government is considering tighter regulatory standards for export-quality AYUSH drugs and if so, the details thereof?

ANSWER

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

(SHRI PRATAPRAO JADHAV)

(a) and (b) The mechanisms to ensure safety, efficacy and quality control of Ayush formulations and details of Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) are as follows: -

1. 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 in compliance with the Good Manufacturing Practices (GMP) as per Schedule T & Schedule M-I of Drugs Rules, 1945 respectively including safety, effectiveness and quality standards of drugs given in the respective pharmacopoeia.

2. Drug Inspectors collect medicine samples regularly from manufacturing firms or 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 products from the market and appropriate legal actions as per Drugs and Cosmetics Act, 1940 and Rules made thereunder.

3. 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. As per the Drugs & Cosmetics Act, 1940 and rules thereunder, the compliance to this 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 & TLC Atlas on 392 single drugs incorporated in API are also published. 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.

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.

5. 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.

6. Pharmacovigilance Program for Ayurveda, Siddha, Unani, and Homoeopathy (ASU & H) Drugs is one of the components under the AOGUSY Scheme of Ministry of Ayush. This is established with an objective of improving patient healthcare and safety in relation to the use of medicines, developing culture of documenting adverse effects, promoting education and training in Pharmacovigilance, and surveillance of misleading advertisements appearing in the print and electronic media.

(c) and (d) Ministry of Ayush is running/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.

Further, 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. Activities carried out by Research councils under Ministry of Ayush encouraging research and evidence generation for AYUSH-based therapies are placed at Annexure I.

(e) The Ayush Grid is a comprehensive digital initiative aimed at transforming the Ayush sector through the power of information and communication technology (ICT). It is aligned with the Ayushman Bharat Digital Health Mission (ABDM). Ayush Grid specifically doesn’t collect any data on traditional medicine.

(f) The quality parameters included in the Pharmacopoeias and Formularies of Ayurveda, Siddha, Unani & Homoeopathic (ASU&H) drugs prescribing mandatory regulatory standards have been identified to align the parameters prescribed by WHO/other major pharmacopoeias prevalent worldwide. These Pharmacopoeias and Formularies are also included in WHO-Index of World Pharmacopoeias and Pharmacopoeial Authorities. Implementation of these pharmacopoeial standards ensures that the medicines conform to optimum quality standards in terms of identity, purity and strength.

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 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 domestic and international standards respectively.

Ayush Export Promotion Council (AYUSHEXCIL) is established by the Ministry of Ayush, Government of India and supported by Ministry of Commerce to promote the export of products and services related to Ayush systems. Directorate General of Foreign Trade has authorized AYUSHEXCIL to issues Registration Cum Membership Certificate and has recently been authorised to issue Certificate of Origin (COO). COO is a regulatory document for exports in international trade, required by customs authorities in the importing country to verify the origin of goods and determine applicable tariffs, taxes, and trade regulations. It also helps ensure compliance with free trade agreements and other trade policies.

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Annexure I

Activities carried out by Research councils under Ministry of Ayush encouraging research and evidence generation for AYUSH-based therapies are as follows: -

1. Central Council for Research in Ayurvedic Sciences (CCRAS) has developed three guidelines for validation /research of the Ayush approach and drugs namely:

   - General Guidelines for Drug Development of Ayurvedic Formulations.
   - General Guidelines for Safety/Toxicity evaluation of Ayurvedic formulation.
   - General Guidelines for Clinical Evaluation of Ayurvedic Interventions.

2. CCRAS has generated scientific evidence of clinical efficacy and safety of 182 classical Ayurveda formulations in 40 disease conditions through clinical trials. The Council is also conducting scientific validation of new combinations (coded drugs) through systematic process of drug development viz. drug standardization and quality control, preclinical safety/toxicity studies and biological activity studies (as appropriate) and clinical trials as per requirement. Further, the Council is in active collaboration with institutes of national repute such as All India Institute of Medical Sciences (AIIMS), Banaras Hindu University (BHU), Indian Institute of Technology (IIT) Delhi, Indian Council of Medical Research (ICMR), Council of Scientific & Industrial Research (CSIR), Jawaharlal Nehru University (JNU) etc. During the financial year 2024-25, 8 collaborative research projects have been completed.

3. To encourage research and evidence generation for Unani Medicine based therapies; the CCRUM involve Unani Medicine Experts and Modern scientists including Pharmacologists, Bio-chemists, Botanists, Pathologists, Microbiologists and Chemists etc. for planning and finalization of the Intramural and collaborative studies protocols. These studies are monitored by Scientific Advisory Committee (SAC) and Research Sub-committee at Headquarters and Institutional Multi-disciplinary Research Advisory Committee (IMRAC) & Institutional Ethics Committees (IEC) at Peripheral Institutes. All of these committees involve Multidisciplinary experts so that evidence-based Unani Medicine therapies and products may be developed. The Council is following all the

Guidelines to ensure that Unani Medicine research is conducted with rigorous scientific methodology, transparency, and accountability. The Research Drugs are being is manufactured by the Councils GMP certified Pharmacy at Hyderabad and Chennai.

4. Central Council for Research in Homoeopathy undertakes research activities such as Clinical Research, Drug Proving, Drug Verification, Drug validation, Drug Standardization, Public Health Research, Fundamental Research and Epidemic research either in intramural mode or in collaboration with different Universities/ institutes of repute. CCRH has 27 institutes/Units and 06 Homoeopathic treatment centers across the country which undertake research in the aforementioned fields, which help in promoting and development of Homoeopathic system of medicines. CCRH has signed 12 MoU and 01 Letter of Intent in the field of homoeopathic medicine with medical centres/hospitals, Universities and Scientific institutes/organisations in Germany, Canada, USA, UK, Argentina, Israel, Armenia, Mexico and Brazil. These Memorandum of Understanding (MoU) are broadly aimed at strengthening & developing co-operation in the field of Research & Education in Homoeopathic system of Medicine. This encompasses joint research projects; exchange of information; organisation of seminars/workshops etc. Academic chair in Homoeopathy has also been established through MoU with Yerevan State Medical University, Government of Armenia to promote education and spread of Homoeopathy.