

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**RAJYA SABHA
UNSTARRED QUESTION NO. 1763
TO BE ANSWERED ON 19th DECEMBER, 2023**

“Qualitative production and distribution of AYUSH medicines”

1763. Shri Naresh Bansal:

Shri Kailash Soni:

Shri Ajay Pratap Singh:

Shri Neeraj Shekhar:

Will the Minister of AYUSH be pleased to state:

- (a) the steps taken by Government for qualitative production and distribution of AYUSH drugs;
and
(b) the steps to be proposed by Government to broaden and intensify the research in AYUSH medicines?

**ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)**

(a)As prescribed in Drugs and Cosmetics Act 1940 and Rules made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathy drugs, is vested with the State Drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government. 158-B in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic, Siddha, Unani medicines and Rule 85 (A to I) in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathy medicines. 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 and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) under Ministry of Ayush, lays down the Formulary specifications and Pharmacopoeial Standards for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs. The quality standards monographs published by PCIM&H are official as per the regulatory provisions of Drugs and Cosmetics Act, 1940 and Rules made thereunder for compliance by the Ayurvedic drug manufacturers.

Rule 160 A to J of the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratory 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. As on date, 35 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 102 laboratories are approved or licensed under the provisions of Drugs and Cosmetics Rules, 1945 for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials.

(b) 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 invitro-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 also in collaboration with various Universities, Hospitals and Institutes.

Further, the 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 Aysuh (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.

National Commission for Indian System of Medicine (NCISM) has taken steps to broaden and intensify the research through PG institutes, wherein Researches are conducted as a part of dissertation. Initiatives taken by NCISM in association with Research Councils, National Institutes and Colleges to promote research activities are at annexure-I.

National Commission for Homoeopathy (NIH) encourages Homoeopathy Medical professionals to adopt latest medical research in their work and contribute to research in Homoeopathy. Steps taken by NCH to contribute to research in Homoeopathy in association with Research Councils, National Institutes and Colleges are at annexure-II.

Initiatives taken by NCISM in association with Research Councils, National Institutes and Colleges to promote research activities are as follows:

1. SPARK PROGRAM.
2. PG-STAR PROGRAM.
3. LITERARY RESEARCH.
4. PUBLICATION GRANT FOR ASU COLLEGES.
5. ANVESHANAM: R A S A - B H A S M A .
6. NCISM has trained 60 master trainers well-oriented in publication ethics, research integrity and scientific writing so as to train all PG guides of ASUS post graduate institutions across the country.
7. A cell namely RESEARCH & INNOVATION CELL has been introduced by NCISM under Draft of Minimum Essential Standards, Assessment and Rating for Undergraduate Colleges and Attached Teaching Hospitals Regulation, 2023 for Ayurveda, Siddha and Unani, which shall facilitate activities related to innovation, incubation, research, publication and IPR (Intellectual Property Rights). The Institutional Innovation Committee (IIC) will identify/invite the innovative ideas from the students, teachers and other staff of the institute to facilitate/incubate/nurture the ideas and to translate to useful products/outcome.

Steps taken by NCH to contribute to research in Homoeopathy in association with Research Councils, National Institutes and Colleges are as follows:

- (a) National Commission for Homoeopathy has notified the Homoeopathy Graduate Degree Course-B.H.M.S regulation on 7.12.22 wherein Research Methodology subject is introduced at undergraduate level to promote young researchers.
- (b) For each department in Homoeopathy Medical College, methodology for supplementing modern advancement, research and technology in homoeopathy (SMART-Hom) is included in regulation.
- (c) For faculty development, online clinical research training was conducted by Commission in collaboration with Central Council for Research in Homoeopathy during June-July 2022. Total 600 faculty and 2300 PG students participated in the training.
- (d) It was recommended to have research journals subscription and research library in Homoeopathy medical colleges to motivate the faculty and students for conducting research.
- (e) Homoeopathy medical colleges are guided to maintain systematic documentation of cases being treated at attached hospitals for proper analysis and for undertaking future research.
- (f) Regulation of medical research in Homoeopathy 2023 is notified by the NCH on 4.12.23 and available on the website of NCH www.nch.org.in