GOVERNMENT OF INDIA
MINISTRY OF AYUSH
RAJYA SABHA

UNSTARRED QUESTION NO. 814
TO BE ANSWERED ON 03rd December 2024

"AYUSH Products"

814. Shri Sanjay Singh:

Will the Minister of Ayush be pleased to state:

(a) the policies implemented to ensure quality, efficacy, and safety of AYUSH products;
(b) the advertising regulation measures taken up to prevent misinformation and false claims;
(c) whether the Ministry can provide the data related to the clinical trials with regard to those major AYUSH products that have been promoted; and
(d) the manner in which prescribing of allopathic medicines by AYUSH practitioners be controlled in view of antimicrobial resistance?

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH
(SHRI PRATAP RAO JADHAV)

(a) Under Rule 158 B of The Drugs Rules, 1945, guidelines for issue of license and requirement of safety study and Experience/Evidence of effectiveness with respect to Ayurveda, Siddha or Unani drugs has been prescribed. 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 have 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 The Drugs and Cosmetics Act, 1940 or the rules made thereunder.

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 Ayurveda, Siddha and Unani drugs (ASU) is vested with the State Drug Controllers/State Licensing Authorities appointed by the concerned State / Union Territory Government.

Rule 160 A to J 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 Ayurvedic, Siddha and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurveda, Siddha and Unani 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 Rules, 1945 for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials.

PCIM&H on behalf of Ministry of Ayush lays down the Formulary specifications and Pharmacopoeial Standards for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs, which serve as official compendia for ascertaining the Quality Control (identity, purity and strength) of the ASU&H drugs, included herein, as per The Drugs & Cosmetics Act, 1940 and Rules 1945, hereunder and compliance to these quality standards are mandatory for the production of 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. So far, 2259 quality standards on raw materials (Single Drugs of Plant/Animal/Mineral/Metal/Chemical origin) used in ASU&H has been published. 405 quality standards of ASU formulations also have been published in respective Pharmacopoeias. Further, 2666 formulary specifications of ASU drugs also published in Formularies of respective system. In addition to above, supporting documents in the form of Macro-Microscopic & TLC Atlas on 351 single drugs incorporated in API are also published. 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 Govt. agencies as per The Drugs & Cosmetics Act & Rules 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.

(b) The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules thereunder encompass the provisions for prohibition of misleading advertisements and exaggerated claims of drugs and medicinal substances including Ayush medicines and for the penalty to be imposed on the defaulters.

Further, Ministry of Ayush has formulated a Central Sector Scheme-Ayush Oushadhi Gunvatta evam Uttpadan Samvardhan Yojana (AOGUSY). One of the components of this scheme is Pharmacovigilance Program for ASU & H Drugs. Under this Program the major objectives are to keep vigilance over ASU&H drugs and to reduce the pollution of misleading advertisements. The program is working through a three-tier network of a National Pharmacovigilance Centre (NPvCC), 05 Intermediary Pharmacovigilance Centres (IPvCs) and 99 Peripheral Pharmacovigilance Centres (PPvCs) established across the country. Through this channel of Pharmacovigilance centres objectionable/misleading advertisements are regularly reported to the respective State Licensing Authorities. Also, as per The National Commission for Indian System of Medicine Regulations 2022 and The National Commission for Homoeopathy regulations 2022, Pharmacovigilance is a mandate component for all the Ayush system of medicine. Under Pharmacovigilance Program for ASU&H drugs consumers can lodge complaints either directly or through online portal: https://www.ayushsuraksha.com.

(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 in vitro-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.

The research outcomes of the clinical trials are being published in peer reviewed journals. Central Council for research in Ayurvedic Sciences (CCRAS) has undertaken clinical studies to validate the clinical efficacy and safety of classical Ayurveda medicines in various disease conditions.

Also, CCRAS has undertaken research for development of new combinations (coded drugs) in various disease conditions which are under different phases of drug development. The research is being carried out 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 adopting prevalent guidelines such as Good Clinical Practices Guidelines for Ayurveda, Siddha and Unani drugs (GCP-ASU), Ministry of Ayush and Ethical guidelines for Bio-Medical Research (Indian Council of Medical Research), World Health Organization (WHO) guidelines for traditional medicines etc. as per requirement.

(d) No information is available regarding the manner of prescribing of allopathic medicines by AYUSH practitioners. As health is a state subject, prescription of allopathic medicines by registered Ayush practitioners falls under the purview of State/UT governments.

National Commission for Indian System of Medicine (Ethics and Registration) Regulations, 2023 and National Commission for Homoeopathy (Professional Conduct, Etiquette and Code of Ethics for practitioners of Homoeopathy) Regulations, 2022 have provisions for standards of Professional Conduct, Etiquettes, and Code of Ethics for Ayush practitioners.

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