GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO. 2721
TO BE ANSWERED ON 25th March 2024

"Regulation and standardization of AYUSH products and practitioners"

2721. Shri Sanjay Singh:
Shri Rajeev Shukla:

Will the Minister of Ayush be pleased to state:

(a) whether there is any policy or scheme of Government to ensure quality, safety and efficacy of AYUSH products and medicines, if so, the details thereof;

(b) whether the Ministry is adopting any measures to ensure that practitioners of AYUSH medicine follow professional standards and ethical guidelines, if so, the details thereof; and

(c) whether the Ministry is taking any steps to regulate the manufacturing and marketing of AYUSH products especially in respect of herbal medicines so as to prevent fraud and harm to consumers, if so, the details thereof?

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

(a) & (c) Yes Sir, In the year 2021, Ministry of Ayush has implemented a Central Sector Scheme- Ayush Oushadhi Gunavatta Evam Uttpadan Samvardhan Yojana (AOGUSY), the total Budget allocation to this scheme is Rs. 122.00 Crores for five years. The components of AOGUSY scheme are as follows:

1. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.
2. Pharmacovigilance of ASU&H drugs including surveillance of misleading advertisements.
3. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.

4. Support for development of standards and accreditation/certification of Ayush products & materials in collaboration with Bureau of Indian Standards (BIS), Quality Control of India (QCI) and other relevant scientific institutions and industrial R&D centres.

The objectives of the Scheme are as under;

1. To enhance India's manufacturing capabilities and exports of traditional medicines and health promotion products under the initiative of Atmanirbhar Bharat.
2. To facilitate adequate infrastructural & technological upgradation and institutional activities in public and private sector for standardization, quality manufacturing and analytical testing of Ayush drugs & materials.
3. To strengthen regulatory frameworks at Central and State level for effective quality control, safety monitoring and surveillance of misleading advertisements of Ayush drugs.
4. To encourage building up synergies, collaborations and convergent approaches for promoting standards and quality of Ayush drugs & materials.

The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 have exclusive regulatory provisions for Ayurvedic, Siddha, Unani, and Homoeopathy (ASU&H) drugs. Provisions relating to Ayurveda, Siddha and Unani Drugs are contained in Chapter IVA and Schedule- I of the Drugs and Cosmetics Act, 1940 and in Rules 151 to 169, Schedules E(I), T & TA of the Drugs Rules, 1945 pertain to ASU&H drug. Further, second schedule (4A) of the Drugs and Cosmetics Act, 1940 provides standards for Homoeopathic drugs and Rules 2dd, 30AA, 67 (C-H), 85 (A to I), 106-A, Schedule K, Schedule M-I of the Drugs Rules, 1945 pertain to Homoeopathic drugs.

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, are vested with the State Drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government. Rule 158-B in the Drugs 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 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 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, which serve as official compendia for ascertaining the quality control (identity, purity and strength) of the 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 and compliance to these quality standards are mandatory for the production of ASU&H drug being manufactured, sell and stocked in India. Implementation of these Pharmacopoeial standards ensures that the medicines conform to optimum quality standards in terms of identity, purity and strength.

Rule 160 A to J of the Drugs 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.

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, which appear in the print and electronic media and Ministry of Ayush has issued advisories and gives direction to SLAs to enforce and regulate as per the provision of this Act.

Ministry of Ayush implemented a Pharmacovigilance Program for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs as a component of Ayush Oushadhi Gunvatta evam Uttpadan Samvardhan Yojana (AOGUSY) scheme under its Central Sector Scheme. The pharmacovigilance program is working through a three-tier network of a National Pharmacovigilance Centre (NPvCC), Five Intermediary Pharmacovigilance Centre's (IPvCs) and 99 Peripheral Pharmacovigilance Centres (PPvCs) established across the country. These centres are mandated to monitor and report the misleading advertisements to the respective State Regulatory Authorities for suitable action against the defaulter. Till date approximately 358 brands of Ayush have been issued the notice for exploiting various regulations.

(b) Under the Ministry of Ayush, the National Commission for Indian System of Medicine (NCISM) and the National Commission for Homoeopathy (NCH) are the two statutory regulatory bodies. These bodies regulate the education, practice, and professional conduct within their respective fields.

In the National Commission for Indian System of Medicine (NCISM) (Ethics and Registration) Regulation 2023, under chapter-IV, Standards of professional conduct, etiquettes and code of Ethics has been defined. Further certain penalties are also prescribed under Chapter-V for practitioners who indulge under improper conduct. It is also state that as per section 31(2) State Medical Council confer power to disciplinary action. For sensitizing the practitioner's/Stake holders NCISM/ Board of Ethics and Registration have conducted more than 25 State-level meetings under the guidance of President Board Ethics and Registration.

The National Commission for Homoeopathy (NCH) maintain professional standards by implementing the provisions of NCH (Professional Conduct, Etiquette and Code of Ethics for Practitioners of Homoeopathy) Regulation 2022, through the State Homoeopathic Councils/Boards.

****