GOVERNMENT OF INDIA MINISTRY OF AYUSH

LOK SABHA STARRED QUESTION No.114 ANSWERED ON 9TH FEBURARY, 2024

Integration of Traditional Medicines in National Health System

*114 SHRI RANJEETSINGH NAIK NIMBALKAR: SHRI DILIP SAIKIA:

Will the Minister of AYUSH be pleased to state:

- (a) whether the Government proposes to formulate any plan to integrate aspects like standardization, quality and safety of traditional and complementary medical system into the National Health System and also to disseminate those at the international level;
- (b) if so, the details thereof and if not, the reasons therefor; and
- (c) the details of fresh steps taken/proposed to be taken by the Government for preserving the rich heritage of traditional and complementary medicines as well as making it modern, authentic and globally acceptable?

ANSWER

THE MINISTER OF AYUSH (SHRI SARBANANDA SONOWAL)

(a) to (c) A Statement is laid on the Table of the House.

The Statement referred to in reply to Lok Sabha Starred Question No. 114 for 9th February, 2024

(a) & (b) National Health Policy- 2017 *inter-alia* recognizes the need to standardize and validate Ayurvedic medicines and establish a robust and effective quality control mechanism for Ayush drugs.

Ministry of Ayush has established Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), as its subordinate office. 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, as per Drugs & Cosmetics Act, 1940 and Rules 1945, framed thereunder. The compliance to these quality standards are mandatory for the production of ASU&H drugs being manufactured in India. 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. Implementation of these pharmacopoeial standards ensures that the medicines reaching to masses conform to optimum quality standards in terms of identity, purity and strength.

The Drugs & Cosmetics Act, 1940 and Drugs & Cosmetics Rules, 1945 have exclusive regulatory provisions for Ayurvedic, Siddha and Unani (ASU) medicines. Section 3(a), 3(h)(i) of the Act exclusively pertain to ASU medicines and similarly regulatory provisions for Ayurvedic, Siddha and Unani drugs are prescribed in Rules 151 to 170 of Drugs & Cosmetics Rules, 1945. As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 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.

Ministry of Ayush has implemented a Central Sector Scheme Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) on 16.03.2021 with total allocation of Rs. 122.00 crores for five years. The components of scheme are as under:

- A. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.
- B. Pharmacovigilance of ASU &H drugs including surveillance of misleading advertisements.
- C. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.
- D. 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 Research & Development Centres.

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) are autonomous organizations under Ministry of Ayush for research in Ayurveda, Unani, Homoeopathy, Siddha and Yoga & Naturopathy respectively and these councils are conducting different research activities through their peripheral institutes available in different parts of the country. CCRAS, CCRUM, CCRH, CCRS and CCRYN are working towards the

scientific validation in the concerned system of medicines through clinical research, drug research, medicinal plants research, fundamental research, literary research and documentation.

In addition, Memorandum of Understanding is signed between the Ministry of Ayush and the Quality Council of India (QCI), through its Board, National Accreditation Board for Hospitals & Healthcare Providers (NABH), for NABH AYUSH entry level certification (AELC) of Ayush Health & Wellness Centers (AHWCs) which has been established by upgrading existing Ayush dispensaries and integrated Ayush hospitals supported under the NAM scheme. Accordingly, at present, 390 AHWCs have been approved for certification as per the decision of Certification Committee.

Ministry of Ayush also developed a Central Sector Scheme for Promotion of International Co-operation in Ayush under which various activities/initiatives has been undertaken or being undertaken for the promotion, propagation & to disseminate Ayush system of medicine globally i.e. offering Ayush scholarships to foreign nationals for undertaking Ayush courses in recognized Ayush institutions in India; collaboration with Foreign Countries by signing of country level MoU for undertaking Ayush related activities on mutual interest; signing of MoUs with foreign institute research/academic collaboration; establishment of Ayush Chairs Universities/Institutes; deputation of Ayush expert (short term/long term); collaboration with WHO or UN agencies for cooperation in the field of Ayush, support or organizing international training; conference, seminar, expo etc. in India or abroad for promoting and strengthening awareness and interest about Ayush Systems of Medicine at international level; establishment of Ayush cell (center) in foreign countries to provide authentic information about Ayush system; representing Ayush in various multilateral forums like- Brazil, Russia, India, China and South Africa (BRICS), Shanghai Cooperation Organisation (SCO), G20, IBSA, Association of Southeast Asian Nations (ASEAN), Bay of Bengal Initiative for Multi-Sectoral Technical and Economic Cooperation (BIMSTEC) etc., support for undertaking clinical research in Ayush at international level etc.

(c) The Traditional Knowledge Digital Library (TKDL) was conceptualised and initiated in 2001 as a collaborative effort between the Council of Scientific and Industrial Research (CSIR) and the Department of Indian Systems of Medicine & Homeopathy (now Ministry of Ayush). The TKDL database currently contains Indian traditional medicine knowledge from classical/ traditional books available in public domain related to Ayurveda, Unani, Siddha & Sowa Rigpa as well as Yoga practices in a digitized format and is available in five international languages (English, French, German, Spanish and Japanese). The value-added content of over 4.6 lakh formulations in TKDL provides contemporary, equivalent terminologies relating to ingredients, metrics, disease conditions, etc. Thus, the TKDL not only protects the traditional knowledge related to medicinal systems, but also preserves the knowledge in a format and language understandable and accessible to patent examiners, researchers and practitioners.

Ministry of Ayush signed a Donor Agreement with World Health Organization (WHO) towards the implementation of developing a Second Module in the Traditional Medicine (TM) Chapter of the International Classification of Diseases -11 Revision (ICD-11). The document has been launched in January 2024.
