

**GOVERNMENT OF INDIA
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY,
UNANI, SIDDHA AND HOMOEOPATHY
(AYUSH)**

**LOK SABHA
UNSTARRED QUESTION NO. 3958
TO BE ANSWERED ON 4TH JANUARY, 2019**

STANDARDISATION AND CERTIFICATION OF AYUSH MEDICINES

**3958. SHRI TEJ PRATAP SINGH YADAV:
SHRIMATI ANJU BALA:**

Will the Minister of **AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)** be pleased to state:

- (a) whether problems are being faced by the indigenous medical streams for marketing and practicing in foreign countries due to the lack of standardisation and certification of Ayurveda and other AYUSH medicines, if so, the details thereof and the remedial measures taken in this regard;
- (b) whether the Government proposes to establish a separate regulatory body for the standardisation and certification of AYUSH products/ institutions and if so, the details thereof;
- (c) whether there is a need for establishing a start-up venture fund for young AYUSH practitioners to set up new innovative enterprises and if so, the details thereof;
- (d) whether there is also need for a National Healers Network to ensure rights of local communities on knowledge hitherto not disclosed in public domain; and
- (e) if so, the steps being taken by the Government in this regard?

ANSWER

**THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)**

(a): Yes, Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) systems of medicine are not recognized in many foreign countries and have to face problems in doing the practice and marketing for want of enabling regulatory provisions. In India, the medicinal products of ASU&H systems are manufactured under license in accordance with the exclusive regulatory & quality control provisions, standards and Good Manufacturing Practices prescribed in the Drugs and Cosmetics Act, 1940 and the Rules thereunder and these products are often exported as food supplements, dietary supplements, health supplements etc fulfilling the specific regulatory requirement of the importing

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countries. Quality standards of ASU&H drugs including the parameters of identity, purity and strength and permissible limits of heavy metals, pesticide residue, aflatoxins and microbial load are published in the respective Pharmacopoeias. Certification of compliance to Good Manufacturing Practices (GMP) is mandatory for grant of manufacturing license by the State Licensing Authority and two voluntary certification systems based on WHO guidelines and international standards are in place to facilitate export of Ayurvedic, Siddha and Unani products. A Central Scheme for promoting AYUSH related International Cooperation has been implemented inter alia with a provision for the industry to avail financial support for registration of ASU&H products in foreign countries, preparation of drug dossiers and participation in international fairs or exhibitions.

(b): The Government of India has set up Pharmacopoeia Commission of Indian Medicine & Homoeopathy and four Pharmacopoeia Committees to develop the standards of Ayurvedic, Siddha, Unani and Homoeopathic drugs and publish respective Pharmacopoeias and Formularies, which are official compendia under the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder. So far, standards of 847 Ayurvedic drugs, 448 Unani drugs, 139 Siddha drugs and 1117 Homoeopathic drugs have been published in the respective pharmacopoeia. Similarly, Ministry of AYUSH has a Drug Control Cell and a vertical structure of AYUSH has been created within Central Drugs Standard Control Organization (CDSCO) to oversee the regulation of Ayurvedic, Siddha, Unani and Homeopathy (ASU&H) drugs from central level and coordinate with the state drug regulatory authorities.

(c): Government has set up Sub-Council on AYUSH under Healthcare Sector Skill Council and there is a proposal under the scheme for champion service sectors through which interested AYUSH stakeholders may be supported for specific skill development programs and young AYUSH practitioners may venture into innovative enterprises.

(d) & (e): An autonomous organization in the name of North Eastern Institute of Folk Medicine, Pasighat (Arunachal Pradesh) has been set up under the aegis of Ministry of AYUSH to strengthen and develop traditional health practices for the benefit of the nation, The main aims and objectives of this institute include functioning as an apex research centre for all aspects of folk medicine knowledge with linkages / networking with other research centers, to create an interface between traditional healers and scientific research and generation of public awareness about the potentials of folk medicine for enhancing public health and of rural communities in particular.

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