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

LOK SABHA
UNSTARRED QUESTION NO.642
TO BE ANSWERED ON 26TH FEBRUARY, 2016

REGULATORY BODY FOR AYUSH

642. SHRI NARANBHAI KACHHADIYA:
SHRI FEROZE VARUN GANDHI:
DR. MANOJ RAJORIA:
DR. SANJAY JAISWAL:
SHRI DILIPKUMAR MANSUKHLAL GANDHI:
SHRI JAGDAMBIKA PAL:
SHRI CHANDRA PRAKASH JOSHI:
SHRI P.P. CHAUDHARY:
SHRI B.V. NAIK:
SHRI S.P. MUDDAHANUME GOWDA:

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

(a) whether the Government is aware the problems being faced by the indigenous medical streams for marketing and practicing in foreign countries due to the 196 lack of standardisation and certification of Ayurveda and other medicines and if so, the details thereof;

(b) whether the Government proposes to establish a centralized/separate regulatory body/agency for the standardisation and certification on AYUSH products and related institutions;

(c) if so, the details thereof along with the role/function and the composition of such body/agency and if not, the reasons therefor for delaying the process for establishing a regulatory body/agency;

(d) the manner in which the Government maintains the balance between the drugs promotion pattern under DCGI and the new body/agency for AYUSH; and

(e) the further steps taken/being taken by the Government to promote scheme for standardisation and certification 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 regulated in many foreign countries; therefore the practice of these systems and marketing of

their medicinal products per se is not allowed in such countries. In India, the medicines of ASU&H systems are licensed and manufactured in the country in accordance with the regulatory provisions, standards and Good Manufacturing Practices prescribed in the Drugs and Cosmetics Act, 1940 and the Rules thereunder and these are often exported as food supplements or dietary supplements because of non-fulfillment of the regulatory requirements of the importing countries. The Government has set up Pharmacopoeia Commission of Indian Medicine & Homoeopathy and Pharmacopoeia Committees to develop the standards of Ayurvedic, Siddha, Unani and Homoeopathic drugs. 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) in the manufacturing unit is mandatory for granting of license by the State Licensing Authority and two voluntary certification systems based on WHO guidelines and Quality Council of India scheme are in place for the industry interested to export Ayurvedic, Siddha and Unani drugs. A Central Scheme for promoting AYUSH related International Cooperation has a provision for the industry to avail financial support for registration of products in foreign countries, preparation of drug dossiers and participation in international fairs or exhibitions.

(b) to (d): Government has considered setting up a structured central regulatory regime for AYUSH drugs. In this regard, the current proposal is to develop a vertical structure for AYUSH in the Central Drugs Standard Control Organization (CDSCO). Accordingly, amendments required in the Drugs & Cosmetics Act, 1940 pertaining to regulation of Ayurvedic, Siddha, Unani, Sowa-rigpa and Homoeopathy drugs have been conceptualized and conveyed to the Department of Health & Family Welfare under whose jurisdiction the proposals of amending Drugs & Cosmetics Act, 1940 and strengthening of CDSCO are being processed. Ministry of AYUSH has notified creation of 12 posts of Deputy Drugs Controllers, Assistant Drugs Controllers and Inspectors of ASU&H and the matter of vertical structure for AYUSH drugs in CDSCO has been followed up regularly with the Department of Health & FW.

(e): Voluntary certification scheme of Quality Council of India has been developed with support from Ministry of AYUSH. 323 products of seven Ayurvedic manufacturers are reported to have been certified under this scheme. Government set up a Task Force under the chairmanship of Prof. H.R. Nagendra with specific terms of reference for development of AYUSH. Report of the Task Force has been received and its recommendations about standardization and certification scheme are being examined in the Ministry of AYUSH.

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