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

LOK SABHA
UNSTARRED QUESTION NO. 2145
TO BE ANSWERED ON 6TH MAY, 2016

REGULATORY FRAMEWORK FOR AYUSH DRUGS

2145. SHRI K.C. VENUGOPAL:
SHRIMATI POONAMBEN MAADAM:

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

(a) whether the Government proposes to set up a Structured Central Regulatory Framework for AYUSH drugs, if so, the details thereof;

(b) the manner in which the said regulatory framework is likely to deal with complaints about misleading advertisements and tall claims of AYUSH medicines;

(c) whether the same will be implemented across the country if so, the details thereof; and

(d) whether the Government also proposes to provide infrastructure, financial and technical support to States to equip their respective regulatory framework, if so, the details thereof?

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

(a): 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 Central Drugs Standard Control Organization (CDSCO) are being processed. Ministry of AYUSH has notified creation of 12 posts of Deputy Drugs Controllers, Assistant Drugs Controllers and Inspectors of Ayurvedic, Siddha, Unani and Homoeopathy.

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(b) & (c): The provisions of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules thereunder are equally applicable to AYUSH medicines and are enforced by the State Governments through the Licensing Authorities. There is a provision under Section 8(1) of the Drugs & Magic Remedies Act, 1954 to authorize Gazetted Officers for searching, seizing and examining advertisements and related documents believed to be in contravention of the provisions of Act and inform Magistrate the seizure of anything to take his orders as to the custody thereof. The Drugs & Magic Remedies Act, 1954 extend to the whole of India except the State of Jammu and Kashmir. The complaints of misleading advertisements and exaggerated claims of AYUSH medicines are forwarded to the concerned State Licensing Authorities for taking action in accordance with the legal provisions.

(d): During 9th to 12th Five Year Plan, financial support has been provided to states for strengthening of the enforcement framework, testing of drugs, capacity building of State Drugs Testing Laboratories and Pharmacies. In 12th Five Year Plan, the Centrally Sponsored Scheme has been merged into National AYUSH Mission, through which financial support is provided to the States in accordance with their Annual Action Plans for quality control activities, infrastructural & functional development of Pharmacies and Drugs Testing Laboratories and engagement of technical manpower. Ministry of AYUSH has published technical documents like Essential Drugs Lists, Good Clinical Practice Guidelines and manual of procedural guidelines for inspection of laboratories.

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