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

LOK SABHA
UNSTARRED QUESTION NO. 141
TO BE ANSWERED ON 21ST JUNE, 2019

QUALITY OF AYURVEDIC MEDICINES

141. SHRI T.N. PRATHAPAN:

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

(a) whether the Government has taken any measures to monitor the quality of Ayurvedic medicines in the country, particularly in the State of Kerala which is home to many traditional Ayurvedic treatment centres and medicine manufacturing units;

(b) if so, the details thereof;

(c) the steps taken by the Government to check the circulation and production of fake Ayurvedic products which are hazardous to health;

(d) whether there is any mechanism to check the advertisements of such fake products; and

(e) 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) & (b): The regulatory and quality control mechanism for Ayurvedic medicines is established in the country in accordance with the exclusive provisions of the Central Drugs & Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945. In this regard, Central Government is vested with the powers to make and amend the legal provisions and to give direction to the State Governments to achieve the objectives of Central Act and the State Governments are responsible to enforce the legal provisions for manufacturing and quality of Ayurvedic drugs. Requirements of complying to the quality standards and proof of safety & effectiveness for licensed manufacturing of Ayurvedic drugs are prescribed in the Drugs & Cosmetics Rules, 1945 and the standards of these drugs are published in the Ayurvedic Pharmacopoiea. Similarly, practice of Ayurveda in the country and in Kerala as well is regulated under the provisions of Indian Medicine Central Council Act, 1970.

Government of Kerala has reported to have taken adequate measures to monitor the manufacturing and sale of Ayurvedic medicines including appointment of Licensing Authority, Drug

Inspectors, Government Analyst and Drug Testing Laboratories. Inspection of manufacturing units is carried out by the Drugs Inspectors, drug samples are tested in the laboratories and legal actions are initiated against violation of the provisions of Drugs & Cosmetics Act 1940 & Rules 1945 and Drugs & Magic Remedies (Objectionable Advertisements) Act 1954 and Rules1955. Efforts of the Kerala State have been supported with grant –in-aid through Centrally Sponsored Scheme of National AYUSH Mission.

(c): Government has set up Pharmacopoeia Commission of Indian Medicine & Homoeopathy and Ayurvedic Pharmacopoiea Committee to develop the standards of Ayurvedic medicines. Good Manufacturing Practices are prescribed under the Drugs & Cosmetics Rules, 1945 and Ayurvedic Pharmacopoiea and Formulary containing standardized formulations and quality standards have been published, which are mandatory for the manufacturing and distribution of Ayurvedic medicines. Misbranded, spurious, adulterated or substandard Ayurvedic medicines, which could be hazardous to human health, are defined in the Drugs & Cosmetics Act along with the penal provisions. For the quality testing of Ayurvedic medicines, a central laboratory and 27 State laboratories are established and 58 laboratories are licensed under the provisions of Drugs & Cosmetics Rules, 1945.

(d) & e): In order to check the veracity of misleading advertisements and exaggerated claims of Ayurvedic and other medicinal products, the Central Government has taken following steps-

i) Regulatory mechanism for prohibition of misleading advertisements and exaggerated claims of drugs including Ayurvedic medicinal products is prescribed in the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules thereunder. Accordingly, State Governments are empowered and have appointed Gazetted Officers to enter and search any premises or examine or seize any record, which contravenes any provisions of the said Act.

ii) Rule 170 under Drugs & Cosmetics Rules, 1945 has been recently notified specifically for prohibition of misleading advertisements of Ayurvedic, Siddha and Unani drugs.

iii) Department of Consumer Affairs has launched an online portal for public complaints against misleading advertisements including advertisements of Ayush products. Complaints registered in the portal against the advertisement of Ayurvedic products are forwarded to the respective State Licensing Authority for appropriate action in accordance with the legal provisions.

iv) Ministry of AYUSH signed a MoU with the Advertising Standards Council of India (ASCI) to undertake monitoring of the misleading advertisements of AYUSH appearing in print and TV media and bring the instances of improper advertisements to the notice of the State Regulatory Authorities for taking necessary action.

v) Ministry of AYUSH has implemented a central scheme of pharmacovigilance under which surveillance of AYUSH drugs related advertisements is done by the identified centres and the defaulters are reported to the concerned State Authorities.

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