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

**LOK SABHA**
**UNSTARRED QUESTION NO.870**
**TO BE ANSWERED ON 14TH DECEMBER, 2018**

# DEFINITION OF HERBAL MEDICINES IN THE DRUGS AND COSMETICS ACT, 1940

**870. KUMARI SHOBHA KARANDLAJE:**
**SHRI PRATHAP SIMHA:**

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

(a) whether it is a fact that there is no exclusive definition of herbal medicines in the Drugs and Cosmetics Act, 1940 and Rules thereunder;

(b) whether the Ayurvedic, Siddha and Unani (ASU) medicines made from herbal/ plant materials and other ingredients are regulated in the country, if so, the details thereof;

(c) whether a number of allegedly misleading advertisements of Ayurvedic and other such products have been reported, during the last three years, if so, the details thereof, year-wise; and

(d) the remedial steps proposed by the Government in this regard, year-wise?

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

(a): Yes, the herbal medicines as such are not defined in the Drugs & Cosmetics Act, 1940 and Rules thereunder. However, with effect from 30th November, 2015 a new category of drugs derived from herbal materials or medicinal plants called as "Phytopharmaceutical drugs" has been included under Rule 2(eb) of the Drugs and Cosmetics Rules, 1945 to provide regulatory provisions for such drugs made from purified and standardized fraction with defined minimum four bio-active or phyto-chemical compounds of an extract of a medicinal plant or its part.

(b): Ayurvedic, Siddha and Unani (ASU) medicines made from plant materials and other ingredients are regulated under the exclusive provisions contained in chapter IVA of Drugs & Cosmetics Act, 1940 and Rules 151 to 169 of Drugs & Cosmetics Rules, 1945. Compliance to Good Manufacturing Practices (GMP) and quality standards of drugs prescribed in the respective pharmacopoeias and submission of proof of safety and evidence of effectiveness are mandatory for the licensed manufacturing of ASU medicines. These legal provisions for ASU medicines are

enforced by the Licensing Authorities/Drug Controllers appointed by the State Governments. Central Government have time to time made regulatory amendments for effective quality control of ASU medicines and issued specific directions/advisories to the State Governments for enforcing the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder.

(c ): Yes, Ministry of AYUSH has come across increasing instances of misleading advertisements/claims allegedly of herbal, Ayurvedic and other such products including 66 cases in 2015, 204 cases in 2016, 547 cases in 2017 and 358 in the current year 2018 as reported from the Grievances Against Misleading Advertisements (GAMA) portal maintained by the Department of Consumer Affairs and the complaints received in this regard from different sources.The Advertising Standards Council of India (ASCI) has reported to have dealt with 732 complaints pertaining to misleading advertisements of AYUSH for the period from 20th January, 2017 to 19th January, 2018.

(d): For checking the veracity of misleading advertisements and to undertake monitoring of such advertisements, powers are vested with the State Governments to authorize Gazetted Officers to search, seize, examine any record, register, document or any other material object related to any objectionable advertisement under the provisions of Section 8(1) of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954. Ministry of AYUSH has repeatedly taken up the matter with the State Governments to appoint Gazetted officers for monitoring of advertisements of ASU&H drugs. It is reported that States have appointed 621 Gazetted officers to enforce the legal provisions for taking necessary action against the defaulters in advertising AYUSH drugs etc. Ministry of AYUSH also signed a MoU with Advertising Standards Council of India (ASCI) in January, 2017 for suo-moto monitoring of misleading advertisements of AYUSH drugs etcappearing in the print media and TV channels and bring the defaulters to the notice of respective State regulators. Media regulators have also been approached to prevent the publication of inappropriate advertisements promoting sale of Ayurvedic and other AYUSH medicines in public interest. On this account, Ministry of Information &Broadcasting issued instructions/guidelines dated 12th July, 2017 to all media channels to advertise only those products which have valid manufacturing license and to abstain from telecasting such misleading advertisements, which are in contravention of the provisions of the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules thereunder. Consumers' complaints about misleading claims or advertisements of AYUSH and herbal medicines registered in the GAMA portal of the Department of Consumer Affairs are examined by a Nodal Officer appointed in the Ministry of AYUSH and are forwarded to the concerned State Regulatory Authorities for necessary action in accordance with the legal provisions. Recently, Ministry of AYUSH issued an Advisory dated 31.08.2018 to the manufacturers and the advertising agencies to refrain from using the name of Government Departments or Institutions in the advertisements of ASU&H Drugs. Also, Caution has been issued in leading newspapers for General public not to fall prey to fake calls and advertisements of ASU&H Drugs.

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