

manufacturers to comply with Central and State Governments have established Drug Testing Laboratories for Ayurvedic medicines and their raw materials and 55 laboratories so far are approved or licensed in the country in accordance with the Drugs and Cosmetics Rules, 1945 for quality testing of Ayurvedic drugs. Quality certification schemes for Ayurvedic medicines are also administered as per WHO Guidelines and International Standards by Central Drug Standards Control Organization (CDSCO) and Quality Council of India (QCI) respectively. Like allopathic medicines Ayurvedic medicines are also covered under the provisions of Drugs and Magic Remedies Objectionable Advertisements Act, 1954 and Rules thereunder. Central Government has initiated pharmacovigilance system for safety monitoring of Ayurvedic medicines etc. and grant in aid is provided through National AYUSH Mission to strengthen quality control activities in the states.

(c) and (d) Drugs and Cosmetics Act, 1940 and Rules thereunder as on date do not have explicit provisions for the clinical trials of Ayurvedic medicines. Rule 158-B of the Drugs and Cosmetics Rules, 1945 does provide the requirement of pilot study to generate proof of safety and effectiveness of certain categories of Ayurvedic medicines. Ministry of AYUSH has published Good Clinical Practice Guidelines for conduct of clinical trials on Ayurvedic, Siddha and Unani medicines on voluntary basis.

#### **Misleading claims and advertisements on herbal medicines**

1602. DR. R. LAKSHMANAN: Will the Minister of AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH) be pleased to state:

(a) whether Government is aware of the fact that categorical definition regarding 'herbal medicines/products' has not been mentioned in Drugs and Cosmetics Act, 1940;

(b) whether Government is also aware of the fact that due to this legislative lacuna misleading claims/misleading advertisements regarding herbal medicines/products are being made in electronic/print media without any let and hindrance; and

(c) the remedial measures proposed by Government in this regard?

THE MINISTER OF STATE OF THE MINISTRY OF AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH) (SHRI SHRIPAD YESSO NAIK): (a) Yes it is true that there is no exclusive definition of herbal medicines in the Drugs and Cosmetics Act, 1940 and Rules thereunder but there are Ayurveda,

Siddha, Unani drugs as defined in Section 3 (a) and (h) of the Drugs and Cosmetics Act, 1940, many of which are made from plant ingredients or herbs.

(b) and (c) Misleading claims and advertisements of all kinds of drugs including herbal medicines/products are regulated under the provisions of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules thereunder. The legal provisions on this account are enforced by the State Governments for prohibiting advertisements, which directly or indirectly give a false impression regarding the true character of the drugs; or make false claims for the drugs or otherwise false or misleading in any material particular. Ministry of AYUSH has signed an MoU with Advertising Standards Council of India (ASCI) on 20th January, 2017 for *suo-moto* monitoring and tracking down the AYUSH related advertisements appearing in print and TV media and directing the advertisers to rectify or withdraw the inappropriate advertisements within the stipulated timeframe. Instances of non-compliance of ASCI directions are forwarded to the concerned regulators for necessary action in accordance with the legal provisions. Penal provisions for the instances of contravention of advertisement norms are prescribed in the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954. Ministry of Information and Broadcasting has issued advisory to all TV Channels to ensure strict compliance of the provisions of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Drugs and Cosmetics Act, 1940 and Rules thereunder. Also, TV Channels have been advised to advertise only licensed AYUSH products. Department of Consumer Affairs is maintaining a portal of Grievances Against Misleading Advertisements (GAMA) for online registration of complaints related to misleading advertisements *inter alia* of AYUSH products and services.

#### **MoU between India and Sri Lanka**

1603. SHRI MAJEED MEMON: Will the Minister of AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH) be pleased to state:

(a) whether Government is planning to ink a Memorandum of Understanding (MoU) between India and Sri Lanka for cooperation in areas of traditional systems of medicine and Homoeopathy;

(b) if so, a detailed note thereon; and

(c) how Government is planning to resource the finances necessary to conduct research, training courses, conferences and meetings and the details thereof?