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

LOK SABHA
UNSTARRED QUESTION NO. 3494
TO BE ANSWERED ON 16TH MARCH, 2018

HERBAL TRADE AUTHENTICATION

3494. SHRI V. ELUMALAI:

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

(a) whether traditional medicines in the large unorganised market contain spurious plant extracts and sometimes heavy metals that pose serious risk for health and if so, the details thereof;

(b) whether the Government is considering to introduce a herbal trade authentication system to address concerns over widespread adulteration; and

(c) 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): The traditional medicines of Ayurveda, Siddha and Unani (ASU) systems including plant extract-based formulations are regulated in the country in accordance with the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder. Manufacturing of such medicines needs grant of license from the concerned State Licensing Authority on compliance to the Good Manufacturing Practices (GMP) and evidence of safety and effectiveness as prescribed in the Drugs & Cosmetics Rules, 1945 and quality standards of identity, purity and strength of the drugs including permissible limits of heavy metals as prescribed in the Pharmacopoeia. Misbranded, Adulterated, Spurious and Substandard ASU medicines are defined in the Drugs & Cosmetics Act, 1940 along with the penal provisions for the defaulters.

(b) & c): Regulatory provisions for herbal products or herbal materials as such are not provided in the Drugs & Cosmetics Act, 1940 and Rules thereunder. However, it is mandatory for the licensed manufacturers of traditional and proprietary ASU medicines to use raw materials matching the quality standards prescribed in respective pharmacopoeias. Quality control provisions including prohibition of adulteration in the manufacturing and trade of such medicines are enforced by the State Licensing Authorities/Drug Controllers. Quality certification system under GMP provisions is provided in the Drugs & Cosmetics Rules, 1945 and quality certification schemes for ASU products in accordance with the WHO-GMP guidelines and international standards are administered by the Central Drug Standards Control Organization and Quality Council of India respectively.

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