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

LOK SABHA
UNSTARRED QUESTION NO. 6544
TO BE ANSWERED ON 6TH APRIL, 2018

TESTING OF TRADITIONAL DRUGS

6544. SHRI SATAV RAJEEV:
DR. HEENA VIJAYKUMAR GAVIT:
SHRIMATI SUPRIYA SULE:
DR. J. JAYAVARDHAN:
SHRI P.R. SUNDARAM:
SHRI MOHITE PATIL VIJAYSINH SHANKARRAO:

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

(a) whether the Government is concerned about the traditional drug manufacturers indulging in unethical business practices mainly due to the absence of a formal protocol on testing of traditional drugs for their safety and if so, the details thereof and the action taken by the Government in this regard;

(b) whether there is any mechanism to do clinical trials for traditional drugs before their products hit the market and if so, the details thereof;

(c) whether the Government has approved any clinics or hospitals in the country to conduct clinical trials for traditional drugs including Ayurveda, Unani, Siddha and Homoeopathy and if so, the details thereof; and

(d) whether the Government proposes to establish Homoeopathy medicine manufacturing unit in the country and 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 drugs of Ayurveda, Siddha and Unani (ASU) systems are regulated in the country in accordance with the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder. Manufacturing of such drugs needs grant of license from the concerned State Licensing Authority on compliance to the Good Manufacturing Practices (GMP), quality

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standards prescribed in the pharmacopoeias including permissible limits of heavy metals, aflatoxins, pesticide residue and microbial load and evidence of safety and effectiveness. Testing parameters and protocols for the quality analysis of these drugs are prescribed in the respective pharmacopoeias. Misbranded, Adulterated, Spurious and Substandard ASU drugs, which may not be safe for human use, are defined in the Drugs & Cosmetics Act, 1940 along with the penal provisions for the defaulters.

(b) & c): The extant Rule 158-B of the Drugs & Cosmetics Rules, 1945 prescribes the regulatory requirement of submission of proof of safety and effectiveness inter alia based on pilot studies for obtaining manufacturing license of various categories of ASU drugs. Ministry of AYUSH has published "Good Clinical Practice Guidelines for conduct of clinical trials in ASU medicine. However, the term 'clinical trial' is not provided in the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder pertaining to manufacturing for sale of ASU drugs under license. There is no legal provision for approving or notifying any specific clinics or hospitals for conducting clinical trials for traditional drugs including Ayurvedic, Siddha, Unani and Homoeopathic drugs.

(d): As of now there is no proposal to establish Homoeopathy medicines manufacturing unit by the central Government in the Ministry of AYUSH. However, through Centrally Sponsored Scheme of National AYUSH Mission (NAM), the grant-in-aid is provided for the establishment and strengthening of State AYUSH manufacturing units including Homeopathy medicines manufacturing units.

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