

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:1702

ANSWERED ON:16.08.2013

INDIAN SYSTEMS OF MEDICINE .

Antony Shri Anto;Anuragi Shri Ghansyam ;Naik Dr. Sanjeev Ganesh;Sule Supriya

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether the present regulatory system is adequate for monitoring of quality, safety and efficacy of Indian Systems of Medicine (ISM) in the country;
- (b) if so, the details thereof and if not, the reasons therefor;
- (c) the present status of the proposal to set up a Central Drug Controller's Office for ISM to be headed by Additional Drug Controller General of India (AYUSH) along with the infrastructure created and the funds earmarked/allocated for the purpose;
- (d) whether the Government proposes to set up laboratories for testing of ISM and if so, the details thereof, State/UT-wise; and
- (e) the details of the proposals received from the States/UTs including Kerala in this regard and the response of the Government thereto during the last three years and the current year, State/UT-wise?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SMT. SANTOSH CHOUDHARY)

(a) & (b): There are adequate provisions under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 for the regulatory framework and for monitoring the quality, safety and efficacy of drugs belonging to Ayurveda, Siddha and Unani (ASU) systems. Licensing Authorities are appointed by the State Governments to oversee the enforcement of legal provisions for the manufacture and sale of ASU drugs. Good Manufacturing Practices and adherence to standards of drugs as prescribed in the pharmacopoeia are mandatory for the manufacturing of licensed products to ensure quality, safety and efficacy of ASU medicines. Ayurveda, Siddha, Unani Drugs Technical Advisory Board (ASUDTAB) and Ayurveda, Siddha, Unani Drugs Consultative Committee (ASUDCC) are statutory bodies under the Drugs and Cosmetics Act to advise the Central and State Governments on technical matters and for securing uniformity throughout the country in the administration of the Act. Department of AYUSH has implemented a Centrally Sponsored Scheme of Quality Control of ASU&H Drugs for strengthening of state pharmacies, Drug Testing Laboratories and Enforcement Mechanism.

(c) The proposal to set up Central Drug Controller's Office for Ayurveda, Siddha, Unani and Homeopathy drugs was sent to Department of Expenditure, Ministry of Finance. 13 posts comprising of one Drug Controller General (AYUSH), five Deputy/Assistant Drug Controllers and seven Drug Inspectors have been agreed to. Allocation of Rs. 102.00 crore has been provided for this initiative in the 12th Plan Budget including Rs. 7.60 crore for the current financial year.

(d): An appellate laboratory - Pharmacopoeial Laboratory of Indian Medicine (PLIM) has been set up by the Central Government. Department of AYUSH in the Ministry of Health & Family Welfare has no proposal in the 12th Plan to set up any laboratory for testing of ASU medicines.

(e): Department of AYUSH has implemented a Centrally Sponsored Scheme for Quality Control of Ayurveda, Siddha, Unani and Homeopathic drugs under which proposals from States including Kerala were received for the Drug Testing Laboratories for providing grant-in-aid. Another proposal from the State Government of Kerala for establishing Drug Testing Laboratory of Ayurveda at Kakkanadu, District- Ernakulam was received in February 2013 and it could not be considered as the relevant Centrally Sponsored Scheme was under review for appropriate modification in the 12th Plan. The State Govt. of Kerala was informed accordingly. State-wise statement of laboratories and quantum of financial assistance granted to them is provided in Annexure-I. The details of State Drug Testing Laboratories given financial assistance as per the schematic pattern during the last three years and current year are presented in Annexure-II.