GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1417
ANSWERED ON:13.12.2013
AYURVEDA SIDDHA UNANI AND HOMOEOPATHIC MEDICINES
Chavan Shri Harischandra Deoram;Rane Dr. Nilesh Narayan

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

(a) the details of the regulatory provisions laid down by the Government to ensure quality, safety and efficacy of Ayurveda, Siddha, Unani and Homoeopathic medicines in the country;

(b) the details of the functional laboratories for testing the quality of Ayurveda, Siddha, Unani and Homoeopathic medicines and the steps taken/proposed by the Government to set up more number of such laboratories, State/ UT-wise;

(c) whether instances of sale of Ayurveda, Siddha, Unani and Homoeopathic medicines in contravention of the regulatory provisions have been reported in the country;

(d) if so, the details thereof and the action taken/proposed by the Government against the offenders during the last three years and the current year and also to enforce strict compliance of quality and safety standards for Ayurveda, Siddha, Unani and Homoeopathic medicines, State/UT-wise; and

(e) whether the Government proposes to set up a patient care registry council for the preservation of documents related to diagnosis and treatment of diseases in the Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy systems of medicines and if so, the details thereof?

Answer

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

(a): There are adequate regulatory provisions under the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 for the regulation and monitoring the quality, safety and efficacy of Ayurveda, Siddha, Unani and Homoeopathy medicines in the country. Licensing Authorities are appointed by the State Governments to oversee the enforcement of legal provisions for the manufacturing of ASU drugs. Guidelines for licensing requirements, Good Manufacturing Practices (GMP) 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 and Rules thereunder.

(b): The details of laboratories for testing quality of Ayurveda, Siddha, Unani and Homoeopathic (ASU&H) medicines are provided in Annexure-I. Central Government has established two appellate laboratories- Pharmacopoeial Laboratory for Indian Medicine (PLIM) and Homoeopathy Pharmacopoeia Laboratory (HPL) under the provisions of Drugs & Cosmetics Act, 1940 to test the drug samples referred from Drug Control authorities and other Government authorities. Department of AYUSH has implemented a Centrally Sponsored Scheme to provide financial support to strengthen the State Drug Testing Laboratories. 27 State Drug Testing Laboratories have been supported through the scheme. In addition, legal provision has been made in the Drugs & Cosmetics Rule 160A-J for approval of institutions to carry out testing of Ayurvedic, Siddha and Unani drugs and the raw materials used in these medicines. National Accreditation Board for Testing and Calibration Laboratories (NABL) accredited laboratories have also been allowed to test ASU& H medicines.

(c) & (d): Details of substandard samples reported by Central Pharmacopoeia Laboratories are given in Annexure-II. Testing reports of the samples are forwarded to the State Authorities for taking necessary action under the provisions of Drugs & Cosmetics Act. In order to enforce standards of ASU&H drugs, GMP has been made mandatory and the pharmacopoeias are included in the Drugs & Cosmetics Rules for compliance of standards of identity, purity and strength of the drugs. Financial supports have been provided through the Centrally Sponsored Scheme for strengthening infrastructural and functional capacity of Drug Testing Laboratories, Pharmacies and enforcement mechanism in the states, testing of drug samples and for in-house quality control laboratories of GMP-compliant manufacturing units. Details in this regard are given in Annexure-III.

(e): Government has enacted Clinical Establishments (Registration and Regulation) Act, 2010 under which National Council for Clinical Establishments has been notified on 19th March 2012. The Act is applicable to clinical establishments of all recognized systems of medicine including establishments of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy (AYUSH) systems of medicine. Under the Act for registration and continuation, every clinical establishment shall fulfill inter-alia provision for maintenance of records and reporting. National Council for Clinical Establishments is assigned with the responsibility of compiling and publishing a

National Register of Clinical Establishments including those of AYUSH systems. Since March 2012 the Clinical Establishments Act has come into force in Arunachal Pradesh, Himachal Pradesh, Mizoram, Sikkim, Union Territories except Delhi and States of U.P., Bihar, Rajasthan and Jharkhand have adopted the Act.