# GOVERNMENT OF INDIA
# AYURVEDA,YOGA & NATUROPATHY,UNANI,SIDDHA AND HOMEOPATHY (AYUSH)
# LOK SABHA

STARRED QUESTION NO:76
ANSWERED ON:27.02.2015
QUALITY OF AYURVEDA SIDDHA UN ANT AND HOMOEOPATHY MEDICINES
Rathod Shri Dipsinh Shankarsinh;Sundaram Shri P.R.

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

(a) the regulatory provisions laid down by the Government to ensure the quality, safety, efficacy and standards of ayurveda, siddha, unani and homoeopathy medicines in the country;

(b) whether manufacturing, marketing and sale of spurious, sub-standard and expired ayurveda, siddha, unani and homoeopathy medicines in contravention of the regulatory provisions have been reported in the country;

(c) if so, the number of such cases reported and investigated, raids conducted and the action initiated/ takcn against the offenders during each of the last three years and the current year, State/UT-wise;

(d) the drugs testing laboratories presently functional for ayurveda, siddha, unani and homoeopathy medicines and the number of these medicines tested and declared spurious/sub-standard/adulterated by them during the said period along with the steps taken/proposed to be taken by the Government to set up more such laboratories, State/UT-wise; and

(e) whether the Government proposes to put in place a separate regulatory system and an independent Central Drug Controller for ayurveda, siddha, unani and homoeopathy medicines and if so, the details and the objectives thereof along with the benefits likely to accrue therefrom?

## Answer

THE MINISTER OF STATE (1C) OF THE MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATH Y(AYUSH) (SHRI SHRIPAD YESSO NAIK)

(a) & (e): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO.76 FOR 27TH FEBRUARY, 2015

(a) The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 provide for the regulation and monitoring of the quality, safety and efficacy of Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) medicines in the country. Licensing Authorities are appointed by the State Governments to oversee the enforcement of legal provisions for the manufacturing and quality control of these drugs. Guidelines for licensing requirements, Good Manufacturing Practices (GMP) and adherence to standards of drugs as prescribed in the pharmacopoeia arc mandatory for the manufacturing of licensed products to promote their quality, safety and efficacy. Ayurveda, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) and Ayurveda, Siddha and 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 there under.

(b) Yes Sir, instances of ASU&H medicines not conforming to the regulatory provisions have been reported.

(c) The information regarding spurious, sub-standard, adulterated and expired ASU&H medicines reported and investigated, raids conducted and action initiated /taken by the State/UT Governments against the offenders during the last three years and current year is enclosed at Annexure-1.

(d) There are two central appellate laboratories named as Pharmacopoieal Laboratory in Indian Medicine (PLIM) and Homoeopathic Pharmacopeial Laboratory (HPL) at Ghaziabad, Uttar Pradesh and 39 approved Drug Testing Laboratories under the provisions of Drugs & Cosmetics Rules 1945. Also, states have 29 Drugs Testing laboratories in the public sector, which had been financially supported by the Central Government for improving their infrastructural and functional capacity. Besides, laboratories accredited by National Accreditation Board for Testing and Calibration Laboratories (NABL) and in-house quality- control laboratories of drugs manufacturing units also undertake testing of undertake testing of ASU&H medicines. List of laboratories is placed at Annexure-2 and the information of testing of medicines as reported by the Central Laboratories is placed at Anncxure-3. The Central Laboratories after carrying out the testing, send the testing reports of the samples to the Stale Authorities for taking necessary action under the provisions of Drugs and Cosmetics Act and Rules thereunder. In order to improve the quality control of ASU&H medicines, provision has been made in the Centrally Sponsored Scheme of National AYUSH Mission (notified in September 2014) to support establishment and strengthening of State Drugs Testing Laboratories and quality testing of medicines.

(e) Presently, the enforcement of regulatory provisions for Ayurveda, Siddha, Unani and Homoeopathy medicines is vested with the State Governments but there is no separate regulatory authority at the Central level. Therefore, considering the distinct nature of Ayurvedic, Siddha, Unani and Homoeopathy medicines and huge size of its industry, the Government, on the recommendation of Ayurvedic, Siddha and Unani Drugs Consultative Committee, has moved a proposal to set up a separate Central Authority. The objective is to oversee the implementation of relevant provisions of the Drugs and Cosmetics Act, 1940 and Rules thereunder and develop improved coordination between Central and State regulatory Authorities for effective quality control of ASIJ&H drugs. Final decision in this regard has not yet been taken.