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

LOK SABHA
STARRED QUESTION NO. 380
TO BE ANSWERED ON 11TH AUGUST, 2017
SPURIOUS AYURVEDIC AND UNANI MEDICINES

†*380. SHRI SATISH KUMAR GAUTAM:

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

(a) whether the Government has received information about supply of spurious Ayurvedic and Unani medicines and if so, the details thereof;

(b) whether the Government has prepared any effective action plan to check the supply of such medicines and if so, the details thereof; and

(c) if not, the reasons therefor?

ANSWER
THE MINISTER OF STATE(IC) OF THE MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (SHRI SHRIPAD YESSO NAIK)

(a) to (c): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 380* FOR 11TH AUGUST, 2017

(a) States have reported cases of sub-standard including spurious medicines and actions taken against them like issue of show cause notices, suspension of licenses, quality testing and legal proceedings. Such instances of alleged default and contravention of legal provisions, brought to the notice of Ministry of AYUSH in the Central Government, are forwarded to the respective State Authorities for taking necessary action in accordance with the legal provisions of drugs quality control.

(b) & (c) The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 have provisions for the regulation and quality control of Ayurvedic and Unani medicines in the country, which are enforced by the State Governments. It is legally mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units & medicines, Good Manufacturing Practices (GMP) and quality standards of drugs given in the pharmacopoeia. Spurious, Adulterated and Misbranded kinds of these medicines and the penal provisions therefor are defined in the Act. Accordingly, the Licensing Authorities/Drugs Controllers appointed by the State Governments are empowered to take necessary action against the defaulters acting in contravention of the legal provisions.

Following steps have been taken by the Government for effective quality control of AYUSH medicines:

1) Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) and Pharmacopoeia Committees have been set up to develop and revise the quality standards and the Standard Operating Procedures for the manufacturing of medicines.

2) Quality standards of 847 Ayurvedic drugs and 448 Unani drugs have been developed and published in the respective pharmacopoeias. Permissible limits of heavy metals, pesticide residue, aflatoxins and microbial load in the medicines are also prescribed.

3) National Ayurvedic and Unani Formularies containing 985 and 1229 standardized formulations along with the methods of their manufacturing have been published.

4) Rule 158-B in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic and Unani medicines in accordance with the proof of safety and effectiveness.

5) Scheduled list of potentially hazardous substances of Ayurvedic and Unani systems is notified under the provisions of Drugs and Cosmetics Rules, 1945. It is mandatory for the manufacturer to label the container with the words "Caution: To be taken under medical supervision" both in English and Hindi languages for the formulations containing such ingredients.

6) Pharmacopoeial Laboratory of Indian Medicine has been established and notified as appellate laboratory under the provisions of Drugs and Cosmetics Rules, 1945 for testing of referred drug samples.

7) 27 State Drug Testing Laboratories and 46 State Pharmacies have been supported for strengthening of their infrastructural and functional capacity. As on date, 55 laboratories are approved or licensed under the provisions of Drugs and Cosmetics Rules, 1945 for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials. Grant-in-aid is provided to the States and UTs under National AYUSH Mission (NAM) for augmenting quality control of these drugs, including strengthening of Pharmacies, Drug Testing Laboratories, enforcement framework and testing of drugs.

8) In order to promote safe use of AYUSH medicines, the Ministry of AYUSH has signed a MoU with the Advertising Standards Council of India (ASCI) to undertake monitoring of misleading advertisements appearing in the print and TV media and bring the defaulters to the notice of the Central Government and the State Regulators for taking necessary action.

9) The Medical Store In-charges of respective systems of medicine and Medicines Inspection Committee (MIC) randomly check the medicines supplied under Central Government Health Scheme. If the store receives any complaint in respect of any medicine, the supply of that medicine is stopped immediately and process of withdrawal of the issued medicine from dispensary or hospital is started. Samples of medicines are sent for testing to Central Laboratory or NABL accredited /Government approved laboratory.

10) Powers are vested with the Central Government under Section 33P of the Drugs & Cosmetics Act, 1940 to give directions to the State Governments as and when required for enforcement of the legal provisions related to Ayurvedic, Siddha and Unani drugs.