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

**LOK SABHA**
**UNSTARRED QUESTION NO. 98**
**TO BE ANSWERED ON 15TH DECEMBER, 2017**

## CLINICAL TRIALS FOR AYURVEDIC MEDICINE

**98. SHRI K. PARASURAMAN:**

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

(a) the total number of permissions granted by the Government for clinical trials for ayurvedic medicines;

(b) whether the Government has constituted regulatory board for Indian traditional medicines on the line of Drugs Controller General of India; and

(c) if so, the details thereof and the steps taken by the Government to regulate production and the sale of Indian traditional medicines?

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

(a): The Government has granted permission for conducting clinical trials on ten Ayurvedic drugs.

(b): Ministry of AYUSH has notified the creation of twelve regulatory posts of Drug Inspectors, Assistant Drug Controllers and Deputy Drug Controllers as a part of the central regulatory framework for administering the provisions of Drugs & Cosmetics Act, 1940 and Rules thereunder pertaining to Ayurvedic, Siddha, Unani and Homoeopathy drugs.

(c ): Recruitment rules for the said regulatory posts have been framed and their approval from Department of Personnel & Training, Union Public Service Commission and Law Ministry is in the process. Meanwhile, additional charge of these posts has been given to the respective Technical Officers of the Ministry of AYUSH till the regular officers are appointed. Manufacturing of Ayurvedic, Siddha and Unani medicines for sale is regulated in the country with the exclusive provisions provided in chapter IVA of the Drugs & Cosmetics Act, 1940 and in Rules 151 to 169 of the Drugs & Cosmetics Rules, 1945. These regulatory provisions are framed and amended by the Central Government on the advice of Ayurvedic, Siddha and Unani Drugs Technical Advisory Board and are enforced by the State

Governments. License is mandatory for the commercial manufacturing of Ayurvedic, Siddha and Unani medicines and following steps have been taken to regulate their production and sale-

**i.** Pharmacopoeia Commission of Indian Medicine & Homoeopathy and Pharmacopoiea Committees have been set up to lay down the quality standards of Ayurvedic, Siddha, Unani and Homoeopathic drugs, which are published in the respective pharmacopoeias and are mandatory for the manufacturers to follow in the manufacturing of these medicines.

**ii.** Good Manufacturing Practices (GMP) and requirements for issue of license to manufacture various types of Ayurvedic, Siddha and Unani medicines on the basis of evidence of safety and effectiveness are prescribed in the Drugs & Cosmetics Rules, 1945.

**iii.** Rules for indicating shelf-life or expiry date on the labels of the ASU&H medicines have been notified and similarly, a provision to display 'caution' for consuming medicines made from potentially hazardous ingredients under medical supervisions is mandatory in the Drugs & Cosmetics Rules.

**iv.** Quality Certification systems for the ASU products have been introduced.

**v.** Central and State Drug Testing Laboratories for ASU drugs are in place and 55 private laboratories have been approved under the Drugs & Cosmetics Rules, 1945 for the quality analysis of ASU drugs and raw materials.

**vi.** Grant-in- aid is provided through the Centrally Sponsored Scheme of National AYUSH Mission for the quality control activities of ASU&H medicines including strengthening of state pharmacies, drug testing laboratories and enforcement framework.

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