

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

**LOK SABHA
UNSTARRED QUESTION NO.1921
TO BE ANSWERED ON 21ST DECEMBER, 2018**

REGULATORY MECHANISM FOR AYURVEDIC MEDICINES

1921. SHRIMATI POONAMBEN MAADAM:

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

- (a) whether the regulatory mechanism for ayurvedic medicines is quite weak in the country;
- (b) if so, the details of the steps being taken by the Government to increase the popularity of ayurvedic medicines;
- (c) whether the Government proposes to make the clinical trial of ayurvedic medicines mandatory; and
- (d) if so, the details thereof and 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) & (b): Drugs and Cosmetics Act, 1940 and Rules thereunder have exclusive provisions for regulation and quality control of Ayurvedic medicines. Accordingly the regulatory mechanism has been evolving in the country in respect of licensed manufacturing and quality parameters of Ayurvedic medicines. Central Government makes and amends the regulatory provisions from time to time on the recommendations of Ayurveda, Siddha and Unani Drugs Technical Advisory Board and the State Governments are responsible to enforce these provisions through the Licensing Authorities, Drug Controller and other regulatory staff. Pharmacopoeia Commission of Indian Medicine & Homoeopathy and Ayurvedic Pharmacopoeia Committee are set up by the Government to develop quality standards of Ayurvedic Drugs and Good Manufacturing Practices (GMP) are prescribed under Drug and Cosmetics Rules, 1945 for compliance by the Ayurvedic Drug manufacturers. Financial support is also provided to the states through Centrally Sponsored Scheme of National AYUSH Mission for strengthening the infrastructural and functional capacity of State Pharmacies, Drug Testing Laboratories and the enforcement framework. Ministry of AYUSH has implemented a number of Central Sector Scheme for promoting and popularizing Ayurvedic and other AYUSH systems of medicine.

(c) & (d): Pilot studies for generating proof of effectiveness of certain categories of Ayurvedic, Siddha and Unani medicines is the requirement prescribed in the Rule 158-B of the Drugs and Cosmetics Rules, 1945 to grant manufacturing license. Any amendment in the Drugs & Cosmetics Rules with regard to Inclusion of clinical trials of Ayurvedic medicines is not intended as of now since there is no such recommendation or proposal under consideration.

.....