

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

**LOK SABHA  
UNSTARRED QUESTION NO. 3266  
TO BE ANSWERED ON 12<sup>TH</sup> JULY, 2019**

**REGULATORY MECHANISM FOR AYURVEDIC MEDICINES**

**3266. SHRI JANARDAN SINGH SIGRIWAL:**

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 and if so, the details thereof and the reasons therefor;
- (b) the details of the action being taken by the Government to increase the popularity of Ayurvedic medicines;
- (c) whether the Government proposes to make the clinical trials 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 Drugs & Cosmetics Rules, 1945 have exclusive provisions for regulation and quality control of Ayurvedic medicines. Central Government makes and amends the legal provisions and issues directions to the State Governments from time to time on the basis of emerging regulatory needs. As such State Governments are responsible to appropriately enforce the regulatory provisions for licensed manufacturing and quality control of Ayurvedic medicines, for which Licensing Authorities, Drug Controllers, Inspectors and Government Analysts are appointed. Ministry of AYUSH has published Essential Drugs List of Ayurveda and extends support through Centrally Sponsored Scheme of National AYUSH Mission for supply of such Ayurvedic medicines to dispensaries & hospitals and for strengthening the infrastructural and functional capacities of the State Ayurvedic Pharmacies, Drug Testing Laboratories, Enforcement Framework to induce effective quality control of Ayurvedic medicines. A number of Central Sector Schemes all also implemented for promoting and popularizing Ayurvedic and other AYUSH medicines.

(c) & (d): Pilot clinical studies for generating proof of effectiveness of certain categories of Ayurvedic medicines is the requirement provided 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 clinical trials of Ayurvedic medicines is not intended as of now since there is no such recommendation or proposal under consideration.