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

RAJYA SABHA
UNSTARRED QUESTION NO. 9
TO BE ANSWERED ON 11TH DECEMBER, 2018

BAN ON CLINICAL TRIAL OF AYUSH DRUGS

9. SHRI M.P. VEERENDRA KUMAR:

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

(a) whether Government has imposed ban on clinical trial of patent drugs of Ayurveda, Siddha and Unani systems;

(b) if so, the details thereof and the reasons therefor;

(c) whether Government has formulated any scheme to check the sale of poor quality Ayush drugs in the market after imposing ban on clinical trial of patent drugs of AYUSH and, if so, the details thereof;

(d) if not, whether Government is considering to formulate any such scheme; and

(e) 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) The Government has not imposed any ban on clinical trial of any kind of Ayurvedic, Siddha and Unani drugs. Rather a set of guidelines of Good Clinical Practice for the conduct of clinical trials on Ayurvedic, Siddha and Unani drugs has been published and a clarification dated 4th July 2018 issued to the State Licensing Authorities about the provisions of Rule 158-B of the Drugs and Cosmetics Rules, 1945 pertaining to the regulatory guidelines for granting license to various categories of Ayurveda, Siddha and Unani drugs on the basis of proof of safety and evidence of effectiveness including pilot studies. Research Councils of Ayurveda, Siddha and Unani systems undertake various research activities including clinical trials.

(c) to (e): Provisions for quality control of Ayurvedic, Siddha, Unani and Homoeopathy drugs manufactured for sale are already inbuilt in the Drugs & Cosmetics Act, 1940 and Rules thereunder along with penalty provisions for misbranded, spurious, adulterated and substandard or poor quality drugs. No new scheme has been formulated and any amendment in the regulatory provisions notified after the issuance of clarification about the requirement of evidence of effectiveness including pilot study for grant of manufacturing license to Ayurvedic, Siddha or Unani drugs.

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