

**GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA**

UNSTARRED QUESTION NO:887
ANSWERED ON:25.02.2011
CLINICAL TRIALS OF AYURVEDIC MEDICINES
Sugumar Shri K.

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

- (a) whether clinical tests or trials of medicines are mandatory before their marketing in the country;
- (b) if so, whether any clinical tests/trials of ayurvedic, unani and homoeopathic medicines have been conducted in the country;
- (c) if so, the details thereof;
- (d) if not, the procedure laid down for scientific validation of the ayurvedic, unani and homoeopathic medicines;
- (e) whether the Central Council for Research in Unani Medicine (CCRUM) has recently undertaken any clinical trials of some formulations to cure certain diseases like malaria and jaundice; and
- (f) if so, the details thereof?

Answer

MINISTER OF THE STATE IN THE MINISTRY OF HEALTH & FAMILY WELFARE (SHRI S. GANDHISELVAN)

- (a) & (d) Under the provisions of Drugs & Cosmetics Act 1940, it is mandatory for only a certain group of Ayurveda, Siddha and Unani medicines to submit evidence of effectiveness for obtaining manufacturing license prior to their marketing in the country. The Ayurveda, Siddha and Unani medicines covered under the definition given in section 3(a) of D&C Act 1940, and to be marketed for indications specified in the authoritative books of First Schedule, are exempted from producing evidence of effectiveness. For Ayurveda, Siddha and Unani (ASU) Patent or Proprietary medicines [covered under definition given in section 3(h) of D&C Act 1940], evidence of effectiveness is required to be submitted for issuance of manufacturing license before their marketing in the country.
- (b) & (c) The evidence of effectiveness required to obtain manufacturing license for Ayurveda, Siddha and Unani (ASU) drugs are submitted to State Licensing Authorities. The data on the studies are therefore available with respective State Licensing Authorities only.
- (e) & (f) Central Council for Research in Unani Medicine (CCRUM) has been undertaking clinical trials of Unani medicine for Malaria and Jaundice at its centers at Kolkatta, Bhadrak, Karimganj, Burhanpur for Malaria and at Lucknow, Hyderabad, New Delhi, Chennai and Mumbai for Jaundice.