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

LOK SABHA
UNSTARRED QUESTION NO. 4433
TO BE ANSWERED ON 19TH JULY, 2019

CLINICAL EFFICACY OF AYURVEDIC MEDICINES

4433. SHRI JAYANT SINHA:

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

(a) the details of the clinical efficacy of ayurvedic medicines; and

(b) the extent to which the clinical efficacy of ayurvedic medicines is tested and evaluated ?

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

(a) & (b): The requirement of proof of effectiveness for traditional/classical and proprietary kinds of Ayurvedic medicines is prescribed under Rule 158-B of the Drugs & Cosmetics Rules, 1945 for the purpose of granting manufacturing license. Textual rationale from authoritative books of Ayurveda as listed in the Drugs & Cosmetics Act, 1940, evidence from scientific literature and proof based on clinical effectiveness data generated from pilot studies are the parameters prescribed in the Drugs & Cosmetics Rules, 1945 for substantiating the intended claims or uses of various kinds of Ayurvedic medicines. Clinical trial is not mandatory for every Ayurvedic medicine, however new indications, new dosage forms and new entities/formulations need to follow the procedure of quality assessment and pre-clinical and clinical safety & effectiveness evaluation for seeking approval from the Licensing Authority to manufacture them for sale and marketing. Ministry of AYUSH has published Good Clinical Practices (GCP) guidelines for conduct of clinical trials in Ayurvedic, Siddha and Unani medicine, which are based on GCP guidelines for conventional drugs. Registration of Clinical Trials of Ayurvedic and other AYUSH drugs/therapies is also done under Clinical Trials Registry – India (CTRI) maintained by the Indian Council for Medical Research (ICMR).

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