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

LOK SABHA
UNSTARRED QUESTION NO. 1522
TO BE ANSWERED ON 4TH MARCH, 2016

CLINICAL TRIAL OF TRADITIONAL DRUGS

1522. SHRI K.C. VENUGOPAL:

Will the Minister of **AYURVEDA,YOGA AND NATUROPATHY, UNANI, S1DDHA AND HOMOEOPATHY(AYUSH)** be pleased to state:

(a) whether the Government is concerned about the traditional drug manufacturers indulging in unethical business practices mainly due to the absence of a formal protocol on testing of traditional drugs for their safety and if so, the actions taken by the Government in this regard;

(b) whether there is any mechanism to do clinical trials for traditional drugs before their products hit the market and if so, the details thereof;

(c) whether the Government has approved any clinics or hospitals in the country to conduct clinical trials for traditional drugs including Ayurveda, Unani, Siddha and Homoeopathy and if so, the details thereof; and

(d) whether the Government proposes to establish Homoeopathy medicine manufacturing unit in Alappuzha, and if so, the details thereof?

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

(a): Quality standards & testing protocols and Good Manufacturing Practices of Ayurvedic, Siddha and Unani (ASU) drugs are prescribed in the pharmacopoeias and Drugs & Cosmetics Rules, 1940 respectively, which are mandatory for the manufacturers to follow. Regulatory provisions for licensing and quality control of ASU drugs are made and amended in consultation with the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board, which is a statutory body set up by the Government under the provisions of Drugs & Cosmetics Act, 1940 to advise the Central and State Governments in technical matters of drugs. 41 laboratories in private sector are approved under the provisions of Drugs & Cosmetics Rules, 1945 and one Central Laboratory and 27 State Laboratories are in place to carry out testing of ASU drugs. Central Research Councils also undertake safety & efficacy studies of classical ASU formulations and support is provided through Extramural Research Scheme to such projects. Since the enforcement of Drugs & Cosmetics Act and Rules thereunder for ASU drugs is vested with the State Governments, complaints and matters concerning safety aspects of these drugs are taken up with the respective states from time to time.

Contd…….

(b) & (c): As per the regulatory provisions prescribed in the Drugs & Cosmetics Rules, 1945, the proof of safety and effectiveness is required for the purpose of licensing of various categories of Ayurvedic, Siddha and Unani drugs. ASU drugs not having textual rationale or evidence in the scientific literature need to undergo safety and efficacy evaluation studies for consideration of grant of manufacturing license. The Government has published Good Clinical Practice guidelines for conduct of clinical trials for Ayurvedic, Siddha and Unani drugs and a directive issued to have these clinical trials registered with the Clinical Trials Registry, India (CTRI). A committee of experts is also in place in the Ministry of AYUSH to examine the proposals of clinical trials seeking permission of the Government. As such there is no provision to approve clinics or hospitals for clinical trials. The pre-requisites for conduct of clinical trials are detailed in the Good Clinical Practice guidelines.

(d): The State Government of Kerala has established 'the Kerala State Homoeopathic Co-operative Pharmacy Limited (HOMCO)' since 1978, which was supported under the Centrally Sponsored Scheme of Drugs Quality Control during the 10th Plan. There is no proposal under consideration of Central Government to set up any Homoeopathy medicines manufacturing unit in Alappuzha.