

**GOVERNMENT OF INDIA
AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMEOPATHY (AYUSH)
LOK SABHA**

UNSTARRED QUESTION NO:3117
ANSWERED ON:07.08.2015
Research and Clinical Trial of AYUSH Medicines
Antony Shri Anto

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

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

- (a) whether the Drug Controller General of India (DCGI) is the overall authority to oversee research and clinical trial of different system of medical sciences including AYUSH in the country;
- (b) if so, the details thereof;
- (c) whether there has been any proposal to establish an independent statutory authority to oversee research and clinical trial in AYUSH including homoeopathy in the country; and
- (d) if so, the details thereof and the action taken by the Government thereon?

Answer

(a) & (b): As per inputs received from the Drugs Division of the Ministry of Health & Family Welfare, clinical trials as defined under Rule 122DAA of the Drugs and Cosmetics Rules, 1945 are regulated by the Drugs Controller General (India). The regulatory guidelines for issue of license based on the evidence of effectiveness and safety of various categories of Ayurveda, Siddha and Unani medicines are prescribed under Rule 158-B of the Drugs and Cosmetics Rules, 1945, which are enforced by the State Licensing Authorities. Ministry of AYUSH has also published Good Clinical Practice Guidelines for Clinical Trials in Ayurveda, Siddha and Unani Medicine. In as far as research is concerned; AYUSH Research Councils have been established by the Government to oversee research activities including the clinical trials related to Ayurveda, Siddha, Unani, Yoga, Naturopathy and Homoeopathy.

(c) & (d): The Government has considered setting up a central regulatory regime for AYUSH medicines. In this regard, the current proposal is to have a vertical structure for AYUSH in the Central Drugs Standard Control Organization (CDSCO). Government has initiated procedural steps required for setting up the vertical structure of AYUSH in the CDSCO. As an interim arrangement Government has set up an Expert Committee headed by Deputy Drugs Controller to consider the clinical trial proposals of AYUSH for grant of permission. For the purpose of research five Research Councils viz Central Council for Research in Ayurveda Sciences (CCRAS), Central Council for Research in Unani Medicines (CCRUM), Central Council for Research in Siddha (CCRS), Central Council for Research in Homoeopathy (CCRH) and Central Council for Research in Yoga and Naturopathy (CCRYN) are established by the Government to oversee research in AYUSH. These Research Councils have 81 units spread across the country, details given in the Annexure.