

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

UNSTARRED QUESTION NO:4720

ANSWERED ON:04.05.2012

GOLDEN TRIANGLE FOR AYURVEDIC MEDICINES

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

- (a) the norms and regulations formulated for registration and scientific validation of ayurvedic, unani and homoeopathic medicines in the country;
- (b) the steps taken/proposed for the proper compliance of the above norms and regulations by the manufacturers of these medicines;
- (c) whether the Government has launched a project called Golden Triangle for the ayurvedic drugs in the country;
- (d) if so, the details thereof; and
- (e) the benefits accrued therefrom?

**Answer**

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

(a) & (b): A free and online public record system called 'Clinical Trials Registry' for registration of clinical trials has since commenced. Clinical trials of Ayurveda, Unani and Homoeopathy are also expected to be registered in the Clinical Trial Registry of India.

The Scientific evaluation of the quality and purity of Ayurvedic, Siddha, Unani & Homoeopathic medicines is done on the basis of pharmacopoeial standards published in the respective Pharmacopoeia. In respect of Ayurveda, Siddha & Unani medicines, the Government has notified on 10th August, 2010, the guidelines for issue of license under which evidence of safety and effectiveness is required for certain categories of patent or proprietary medicines and extracts of medicinal plants. It is for the State licensing authorities to enforce the compliance of the quality standards and other regulatory requirements by the manufacturers of Ayurveda, Siddha, Unani & Homoeopathic medicines.

(c) to (e): Yes. The Golden Triangle Partnership Scheme was initiated as a trilateral collaboration between Department of AYUSH, Central Council for Scientific and Industrial Research (CSIR) and Indian Council of Medical Research (ICMR) to develop new Ayurvedic and herbal products for prioritised disease conditions. CSIR, however, has closed this activity since September 2010. Under the GTP Scheme, following important activities have been undertaken:-

- (a) Chemical characterization and safety evaluation of eight most widely used Ayurvedic mineral preparations.
- (b) The integrated protocol for conducting clinical trials on Benign Prostate Hypertrophy, Osteoporosis, Hypertension and Dyslipidemia have been developed.
- (c) Workshop on Good Clinical Practices and Ethics conducted on above mentioned diseases to Train the Trainers.
- (d) A dossier of codified Ayurvedic formulations for the management of HIV/AIDS patients has been formulated for conducting clinical trials.