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

UNSTARRED QUESTION NO:3372
ANSWERED ON:31.08.2012
CENTRAL DRUG CONTROLLER FOR AYUSH DRUGS
Chitthan Shri N.S.V.;Ganeshamurthi Shri A.;Virendra Kumar Shri

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

(a) whether the Government proposes to set up a Central Drug Controller for AYUSH drugs to ensure the quality and standards of these medicines;

(b) if so, the details thereof along with the funds proposed/allocated for the purpose and the number of regular, contractual and outsourced posts approved/ proposed to support the office of the Central Drug Controller for AYUSH;

(c) whether the Government proposes to make it mandatory for all new patented herbal medicines to undergo human trial before these are introduced in the market;

(d) if so, the details along with the objective thereof; and

(e) the other measures taken/proposed by the Government for quality and standardization of AYUSH drugs in order to boost the acceptability and export of these drugs abroad?

## Answer

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD)

(a): Yes, the Department of AYUSH had moved the proposal of setting up a Central Drug Controller's Office for Ayuveda, Siddha, Unani and Homoeopathy to be headed by Additional Drug Controller General of India (AYUSH).

(b): The EFC chaired by Secretary (Expenditure) approved the proposal on 4th October 2010 for creating 40 posts in the proposed Central Drug Controller's Office (AYUSH) including 25 regular and 15contractual/outsourced posts and for supporting engagement of 330 scientific manpower in the State Drug Testing Laboratories. The matter for creation of required manpower is under examination in consultation with the Department of Expenditure and an allocation of Rs.80 lakhs is made in the annual plan 2012-13 for the purpose.

(c) & (d): The safety and efficacy of a new drug proposed to be introduced for the first time in the country irrespective of its origin is required to be determined in accordance to the provisions under the Drugs and Cosmetic Rules including the human clinical trials wherever considered necessary.

e) In order to boost the acceptability and export of these drugs, the Government have taken following measures to improve quality, safety, and efficacy of these medicines:-

i) Ayurvedic, Siddha, Unani and Homoeopathic (ASU&H) Pharmacopeias have been published containing quality standards of 600 single drugs & 152 compound formulations of Ayurveda, 139 single drugs of Siddha, 298 single drugs and 100 compound formulations of Unani and 1016 Homoeopathic drugs.

ii) Compliance with Good Manufacturing Practices (GMP) has been made legally mandatory for licensing of Ayurveda, Siddha, Unani and Homeopathic drugs.

iii) Pharmacopoeia Commission for Indian Medicine (PCIM) has been established to address quality concerns and develop quality standards for Ayurveda, Siddha and Unani medicines.

iv) Department has launched a scheme for voluntary quality certification of ASU Drugs in collaboration with the Quality Council of India.

v) Shelf life of various categories of Ayurveda, Siddha and Unani drugs and the use of preservatives, additives etc. in the manufacture of these drugs have been notified.

vi) State Drug Testing Laboratories and State Pharmacies have been provided financial assistance for strengthening of infrastructure required for quality testing and production of Ayurveda, Siddha, Unani and Homoeopathic drugs in public sector. 44 Drug Testing Laboratories are approved for testing of Ayurveda, Siddha, Unani and Homoeopathic drugs as per the provisions of Drugs & Cosmetics Rules 1945.

vii) For facilitating export of ASU drugs, exemption in labeling and packing provisions is made in the Drugs & Cosmetic Rules 1945.