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

UNSTARRED QUESTION NO:4046
ANSWERED ON:20.03.2015
CLINICAL TRIAL OF TRADITIONAL MEDICINES
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Will the Minister of AYURVEDA,YOGA & NATUROPATHY,UNANI,SIDDHA AND HOMEOPATHY (AYUSH) be pleased to state:

(a) whether clinical trials of ayurvedic, unani, siddha and homoeopathic medicines have been conducted before their launch in thi country;

(b) ifso, the details thereof and if not, the reasons therefor indicating the procedure laid down for scientific validation of these traditional medicines in absence of a formal protocol to ensure their quality and safety in the country;

(c) whether the Government proposes to set up ayurvedic clinical research centres to help scientifically validate traditional system of healing and if so, the details thereof, State/UT-wise including Kerala;

(d) the other measures being taken by the Government to put in place a formal mechanism/protocol to strengthen the standardization and certification process of the aforesaid traditional medicines in the country; and

(e) the number of traditional medicines launched in the market after successful clinical trial during the last three years and the current year indicating the manner in which their clinical trials were conducted?

Answer

THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (SHRI SHRIPAD YESSO NA1K)

(a) & (b): Chapter IV A of the Drugs and Cosmetics Act, 1940 pertaining to the regulation of Ayurvedic, Siddha and Unani drugs does not have specific provisions for clinical trials as are prescriDed for allopathic drugs. However, Drugs and Cosmetics Rules, 1945 provide regulatory requirements including evidence of safety and effectiveness for licensing of various kinds of Ayurvedic, Siddha and Unani medicines. These provisions were notified in August 2010 and are enforceable by the State Licensing Authorities/Drug Controllers. Central Government has directed all State Licensing Authorities, Research Councils, National Institutes, Heallh Universities and AYUSH Drugs Manufacturers Associations to ensure registration of all clinical trials of AYUSH in the Clinical Triais Registry of India. Guidelines of Good Clinical Practices for conduct of clinical trials in Ayurvedic, Siddha and Unani medicine have also been published. Legally, it is mandatory for the drug manufacturers to observe standards prescribed in the pharmacopoeias and Good Manufacturing Practices notified under the Drugs and Cosmetics Rules. Since March 2007, an Expert Committee has been set up to look in to the applications seeking grant of permission to the AYUSH clinical trials. In respect of manufacturing of new homoeopathic medicines, the Drugs & Cosmetics Rules, 1945 provide the requirement of documentary and other evidence of therapeutic efficacy of the medicine including the minimum proving carried out with it. Validation of Ayurvedic, Siddha, Unani arid Homoeopathic medicines has been taken up by the respective Research Councils.

(c): Government of India has set up Research Councils of Ayurveda, Siddha, Unani and Homoeopathy having 80 research centres spread across the country and an extramural research scheme has been implemented to support project-based research activities. State/UT-wise list of research centres of Ayurveda, Siddha, Unani and Homoeopathy is annexed. Kerala state has informed to have identified three centres to conduct clinical trials and one centre for safety studies.

(d): The Government hat set up Pharmacopoeia Commission of Indian Medicine and Homoeopathy and Pharmacopoeia Committees for standardization of Ayurvedic, Siddha, Unani and Homoeopathic drugs and publication of their pharmacopoeia! standards. Certification systems put in place for these medicines include GMP certification by the State Licensing Authorities in accordance with the provisions of Drugs and Cosmetics Rules, 1945 and voluntary certification by Quality Council of India and certification of medicinal products in accordance with WHO guidelines by the Central Drug Standards Control Organization.

(e): In view of the absence of any specific provisions in Chapter IVA of the Drugs and Cosmetics Act, 1940, information regarding clinical trials of traditional medicines is not maintained by the states.