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

LOK SABHA
STARRED QUESTION NO. 14
TO BE ANSWERED ON 2ND FEBRUARY, 2018
TESTING OF AYUSH MEDICINES

***14. DR. KIRIT P. SOLANKI:**

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

(a) whether any guidelines have been issued by the Indian Council of Medical Research regarding the adherence of standards in testing of AYUSH medicines and if so, the details thereof;

(b) whether the Government has taken steps to bring research on ayurvedic drugs and formulations closer to international standards and if so, the details thereof;

(c) whether the Government has established ethical principles under which drug trials are conducted for research on traditional medicines and proprietary varieties of traditional medicines involving human participation;

(d) if so, the details thereof and if not, the reasons therefor; and

(e) whether the Government has adopted any measures to monitor the testing of ayurvedic and other traditional medicines 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) to (e): A statement is laid on the Table of the House

STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 14* FOR 2ND FEBRUARY, 2018

a) Yes, the 'National Ethical Guidelines for Biomedical and Health Research Involving Human Participants' have been issued by the Indian Council of Medical Research in the year 2017 for observing ethical standards for human research in the country. A dedicated section – 7.13 on 'Clinical trials on Traditional Systems of Medicine' is included in these guidelines.

b) 'Good Clinical Practice Guidelines for Clinical Trials in Ayurveda, Siddha and Unani Medicine (GCP-ASU)' have been published by the Government to address the issue of protection of human rights as a subject in clinical trials and provide assurance of the safety and efficacy of the ASU formulations. These guidelines include standards of how clinical trials should be conducted; and define the roles and responsibilities of clinical trial sponsors, clinical research investigators, monitors etc. The objective is to inculcate the culture of conducting Ayurvedic, Siddha and Unani (ASU) intervention-based clinical studies in the country in accordance with requisite scientific standards and appropriately designed methodologies to bring research on Ayurvedic, Siddha and Unani drugs and formulations closer to international standards. The Central Council for Research in Ayurvedic Sciences set up by the Government is following such standard protocols and guidelines for research on Ayurvedic drugs and formulations and Pharmacopoeia Commission of Indian Medicine & Homoeopathy has international collaboration with US Pharmacopoeia Commission to develop the standard of Ayurvedic drugs. Ministry of AYUSH has also implemented an Extramural Research Scheme to support scientific projects for development of Ayurvedic and other traditional medicines. International collaboration with the institutions in Germany, Hungary, Argentina, USA etc has also been undertaken/explored for scientific studies of AYUSH drugs.

c) & d) Yes, the ethical principles for conduct of research on Ayurvedic, Siddha and Unani medicines/traditional medicines including proprietary varieties of traditional medicines involving human participation are laid down in the two publications, namely the 'Good Clinical Practice Guidelines for Clinical Trials in Ayurveda, Siddha and Unani Medicine (GCP-ASU)' published by Ministry of AYUSH (erstwhile Department of AYUSH) in 2013 and the 'National Ethical Guidelines for Biomedical and Health Research Involving Human Participants' published by ICMR in 2017. The ICMR's Ethical Guidelines- 2017 state that "Research on AYUSH and ASU interventions of Traditional Medicine (TM) including external medicines/therapeutic procedures, folk medicines, and patent and proprietary medicines of TM involving human participants should be conducted in accordance with all the ethical principles described in these guidelines including Serious and Adverse Event reporting and compensation, AYUSH GCP guidelines, as well as other applicable regulations of the country".

e) GCP guidelines for clinical trials on ASU medicines contain the provisions for the sponsors of clinical trials to ensure the studies are adequately monitored. The Government has also inserted Rule 158-B in the Drugs & Cosmetics Rules, 1945 w.e.f. 10th August, 2010 prescribing the requirement of proof of safety and effectiveness based on pilot studies for certain categories of ASU medicines for the purpose of licensing of such medicines. The Government has repeatedly advised the stakeholders to get the clinical trials of ayurvedic and other traditional medicines approved by the Ethics Committee and have them registered with the Clinical Trials Registry of India (CTRI) aimed at safeguarding the interest of clinical trial participants and recording & dissemination of clinical trial information respectively.

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