

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

**LOK SABHA
UNSTARRED QUESTION NO. 130
TO BE ANSWERED ON 21ST JUNE, 2019**

SCIENTIFIC TESTING OF TRADITIONAL MEDICINES

130. SHRI KUNWAR PUSHPENDRA SINGH CHANDEL:

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

- (a) whether the Government is contemplating/has contemplated any policy for the scientific testing of traditional medicines and build a system for the monitoring of the quality and effectiveness of the traditional medicines, if so, the details thereof;
- (b) whether the Government has given sanction to conduct these tests on humans, if so, the details thereof; and
- (c) the details of measures taken by the Government to encourage the export of traditional medicines?

ANSWER

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

(a) & (b): Standards of traditional medicines of Ayurveda, Siddha and Unani (ASU) systems are developed on the basis of scientific parameters, which are prescribed in the respective pharmacopoeias. The Pharmacopoeia Commission of Indian Medicine & Homoeopathy and Pharmacopoeia Committees are engaged with scientific institutions to develop the standards, which are mandatory for the manufacturers of ASU medicines in accordance with the provisions of Drugs & Cosmetics Act, 1940 and Rules there under. Accordingly, the extant Rule 158-B of the Drugs & Cosmetics Rules, 1945 prescribes the regulatory requirement of proof of safety and effectiveness, inter alia based on pilot studies, for licensed manufacturing of various categories of Ayurvedic, Siddha and Unani medicines. Enforcement of these provisions is under the purview of the Licensing Authorities/Drug Controllers appointed by the State Governments. Ministry of AYUSH has published "Good Clinical Practice Guidelines for conduct of clinical trials in Ayurveda, Siddha and Unani Medicine. These guidelines are for voluntary use and encompass the design, conduct, termination, audit, analysis, reporting and documentation of the systematic studies involving human subjects for determining the safety and efficacy of Ayurvedic, Siddha and Unani (ASU) medicines and to ensure that the studies are scientifically and ethically sound and the clinical properties of the ASU medicines under investigation are properly documented. Research Councils under Ministry of AYUSH and the Indian Council for

Medical Research (ICMR) are promoting and carrying out research in the area of traditional medicines through intramural and extramural research activities.

(c): Measures adopted for encouraging the export of Ayurvedic, Siddha and Unani medicines are as under:-

- i) Provision of issuing Free Sale Certificate for the export-oriented ASU medicines is made in the Drugs & Cosmetics Rules, 1945.
- ii) Labelling provisions under Drugs & Cosmetics Rules, 1945 are exempted for ASU medicines exported to other countries.
- iii) System of quality certification under WHO-GMP Guidelines is in place under the administrative purview of Drugs Controller General for facilitating international trade of ASU medicines.
- iv) Quality Council of India has implemented a scheme of certification to grant AYUSH Standard and AYUSH Premium marks of quality to ASU medicinal products.
- v) Good Clinical Practice (GCP) Guidelines published for conduct of clinical trials on ASU medicines.
- vi) Registration of clinical trials of ASU drugs has been included in the Clinical Trials Registry of India (CTRI) maintained by Indian Council for Medical Research (ICMR).
- vii) Morbidity codes and standardized terminology of Ayurvedic, Siddha and Unani systems have been developed on the lines of WHO International Classification of Diseases (ICD).
- viii) Standardization and Research & Development (R&D) of ASU medicines is being promoted by and large done on the basis of integrated protocols and methodologies involving globally acceptable scientific parameters.
- ix) Financial support has been made available to the manufacturers/entrepreneurs for preparation of product dossiers and registration of ASU medicines in foreign markets and for participation in international trade fairs, exhibitions and business meets.
- x) Ministry of AYUSH has established AYUSH Information Cells in Indian Missions and entered into MoUs with foreign countries for promoting international cooperation in the area of traditional medicine, mutual recognition of pharmacopoeias, establishment of Ayush Chairs and for collaborative activities.
- xi) Pharmaceutical Export Promotion Council- Pharmexcil covers export matters of ASU products.