GOVERNMENT OF INDIA
MINISTRY OF AYUSH

LOK SABHA
UNSTARRED QUESTION NO. 3882
TO BE ANSWERED ON 25th March, 2022

SCIENTIFIC VALIDATION AND DOCUMENTATION OF AYUSH DRUGS

3882. SHRI SANJAY KAKA PATIL:

Will the Minister of **AYUSH** be pleased to state:

(a) whether the Government has undertaken steps to initiate more clinical trials to fill up the gap due to lack of evidence based medicines;
(b) if so, the details thereof;
(c) whether the Government has undertaken steps towards scientific validation and strong documentation of AYUSH drugs; and
(d) if so, the details thereof?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) Yes, Sir.

(b) Government has set up separate Central Research Councils for promoting scientific validation of Ayurvedic, Unani, Siddha and Homoeopathic medicines. Further, Ministry of Ayush has taken steps to facilitate clinical trials in Ayush, like publication of Good Clinical Practice in Ayurveda, Siddha and Unani Medicine (GCP-ASU) and Good Clinical Practice in Homoeopathy with the objective that the studies are ethical and scientific so that clinical properties of the ASU&H medicines under investigation are properly documented, issuing directive for registration of AYUSH clinical trials in Clinical Trials Registry of India. Also, Rule 158-B of the Drugs Rules, 1945 specifies for providing the proof of effectiveness and safety of certain categories of Ayurvedic, Siddha and Unani medicines as a pre-requisite for obtaining license.

(c) Yes, Sir.

(d) For Standardization of Indian medicines in the country, the Government has established Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIM&H) under the Ministry of Ayush. The prime mandate of the Commission is to publish and revise Ayurvedic Pharmacopoeia of India (API), Siddha Pharmacopoeia of India (SPI), Unani Pharmacopoeia of India (UPI) and Homoeopathic Pharmacopoeia of India (HPI). The Pharmacopoeial standards are basic need to ensure quality, safety and efficacy of Ayurvedic, Siddha, Unani and Homoeopathic medicines. The Pharmacopoeia Commission is also responsible to publish and revise Ayurvedic, Siddha and Unani official formularies and regulatory compendiums. These published standards become part of Drugs and Cosmetics Act, 1940 and Rules, 1945 for ascertaining the quality standards of Raw materials and finished drugs and are implemented uniformly across India.

Further, the separate Central Research Councils working under the aegis of Ministry of Ayush are working towards the scientific validation of the Ayush systems of medicine through clinical research, pre-clinical research, drug research, medicinal plant research, fundamental research, literary research and documentation. Data of 34333 such research articles published on Ayush systems are available at "ayushportal.nic.in".

Also, Ministry is implementing Central Sector Scheme namely, 'Ayurgyan Scheme Yojana' (erstwhile Extra Mural Research Scheme). Research & Innovation in AYUSH is a component of this scheme and funds are provided to institutions to support and encourage research activities in all streams of AYUSH their scientific validation and documentation. Further, under 'Ayurswastha Yojana' (Central Sector Scheme), financial assistance is provided to Individual Organizations/Institutes through its Centre of Excellence component for Research and Development activities in AYUSH Medicines/Fundamentals/therapeutics etc. and through its Public Health component for documentation of the efficacy of AYUSH interventions in various public health issues which can be taken up in larger scale for implementation in national health programme.

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