GOVERNMENT OF INDIA

MINISTRY OF AYUSH

LOK SABHA

UNSTARRED QUESTION NO.895

TO BE ANSWERED ON 07.02.2025

Regulations for AYUSH

895. Shri Sukhdeo Bhagat:

Will the Minister of AYUSH

be pleased to state:

(a) whether the Ministry has faced any criticism regarding the lack of uniform regulations across traditional medicine systems like Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homoeopathy and if so, the details thereof;

(b) whether it is a fact that as per the Research and Information System for developing countries Report on AYUSH (2022), a lack of standardization has led to significant variations in the quality and safety of treatments, with an estimated 30-40% of AYUSH products being substandard or not meeting safety protocols and if so, the details thereof;

(c) whether it is also a fact that a 2019 WHO report has noted that several AYUSH medicines were found lacking scientific validation and if so, the details thereof;

(d) whether in the light of these concerns, the Government has taken any steps to develop a uniform regulatory framework for these systems and if so, the details thereof; and

(e) the manner in which the Government plan to address these issues, ensuring consistency in product quality and protect public health?

ANSWER

THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH
(SHRI PRATAPRAO JADHAV)

(a) to (c) No Sir.

(d) and (e) The Drugs & Cosmetics Act, 1940 and Drug Rules, 1945 have exclusive regulatory provisions for Ayurvedic, Siddha, Unani, and Homoeopathy drugs. It is mandatory for the manufacturers to comply with the Good Manufacturing Practices (GMP) as per Schedule-T for Ayurveda, Siddha and Unani drugs & Schedule M-I for Homoeopathy drugs prescribed in the Drugs Rules, 1945 and also adhere to with the quality standards of drugs mentioned in the respective pharmacopoeia for obtaining license for manufacturing units & medicines, including proof of safety & effectiveness.

Ministry of Ayush, Government of India has established the Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) as its subordinate office. PCIM&H on behalf of Ministry of Ayush lays down the formulary specifications and pharmacopoeial standards for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs which serves as official compendia for ascertaining the quality (identity, purity and strength) of the ASU&H drugs. As per the Drugs & Cosmetics Act, 1940 and Rules made thereunder, the compliance of these quality standards are mandatory for the production of ASU&H drugs being manufactured in India.

Further, the National Commission for Indian System of Medicine (NCISM) is the statutory body constituted under the provisions of NCISM Act, 2020 for regulating the education and practice of Ayurveda, Unani, Siddha and Sowa-rigpa. Similarly, the National Commission Homoeopathy (NCH) is the statutory body constituted under the provisions of NCH Act, 2020 for Homoeopathy. Both the Commissions have prescribed regulations relating to education and practice related to the respective systems of medicines as per their system specific requirements.

*****