GOVERNMENT OF INDIA MINISTRY OF AYUSH

LOK SABHA UNSTARRED QUESTION NO. 1024 TO BE ANSWERED ON 5th December, 2025

"AYUSH System of Medicine"

1024. Shri Arun Govil:

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

- (a) the manner in which the Government assures the scientific approach towards the manufacturing of the medicines of AYUSH system; and
- (b) the system adopted for determining the prices of AYUSH medicines in the country?

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

(a) Ministry of Ayush, Government of India has established Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) as its subordinate office. PCIM&H 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 thereunder, the compliance to these quality standards are mandatory for the production of ASU&H drugs being manufactured in India. So far, 2269 quality standards on raw materials (single drugs of plant/ animal/ mineral/ metal/ chemical origin) used in ASU&H drugs, 426 quality standards of ASU formulations and 2799 formulary specifications of ASU drugs have been published. In addition to above, supporting documents in the form of Macro-Microscopic & Thin Layer Chromatography (TLC) Atlas on 392 single drugs incorporated in Ayurvedic Pharmacopoeia of India (API) have also been published.

PCIM&H also acts as the Appellate Drugs Testing Laboratory for testing or analysis of ASU&H drugs. In addition, it conducts capacity-building trainings at regular intervals for the standardization, quality control, and testing or analysis of ASU&H drugs for Drug Regulatory Authorities, Drug Analysts, and other relevant stakeholders, with a focus on laboratory techniques and methodologies essential for ensuring the quality of ASU&H drugs.

Further, it is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units & medicines including proof of safety & effectiveness, compliance with Good Manufacturing Practices (GMP) as per Schedule T of the Drugs Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia. As on date, there are 34 State Drug Testing Laboratories and 108 private Drug Testing Laboratories approved or licensed under Rule – 160 A to J of the Drugs Rules, 1945, for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials.

The quality of medicinal plants is ensured by promoting Good Agricultural and Collection Practices (GACP). Digital supply-chain tracking system is available for raw material sourcing and authentication.

Twelve National Institutes and five Research Councils under the Ministry of Ayush are engaged in coordinating, formulating, developing, and promoting research on scientific lines in the Ayush systems of healthcare. Their research covers a wide range of areas, including clinical studies, medicinal plant research, and the standardization and quality control of Ayush medicines.

(b) The Price Control Order applies only to those medicines that are specified under clause (b) of Section 3 of the Drugs and Cosmetics Act, 1940 and are listed in the Schedule provided under Section 2A of the Essential Commodities Act, 1955. These scheduled medicines do not include drugs of the Ayurveda, Siddha, Sowa-Rigpa, and Unani systems.

However, the market prices of Ayush medicines depend on several factors, including fluctuating prices of raw materials, intermediates, packaging materials, etc.

At present, the determination of these costs depends on prices fixed by several other sectors.
