GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO. 165
TO BE ANSWERED ON 22ND JULY, 2025

"Quality assessment of AYUSH drugs"

165. Shri Govindbhai Laljibhai Dholakia:

Will the Minister of *Ayush* be pleased to state:
(a) the measures that the Ministry has implemented in consultation with State Governments and other stakeholders for regular monitoring of quality of AYUSH drugs, particularly in view of reports of adulteration and rejection of some of AYUSH consignments in the international market;
(b) whether the Ministry is running any collaborative programme with Government of Gujarat for identification of medicinal plants in Dang district; and
(c) the steps that the Ministry has taken in partnership with State Governments and other stakeholders to set up specialized laboratories in every State for quality assessment of AYUSH drugs?

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

(a) Ministry of Ayush has implemented following measures for regular monitoring of quality of AYUSH drugs:

1. The Drugs and Cosmetics Act, 1940 and rules thereunder have exclusive regulatory provisions for Ayurvedic, Siddha, Sowa-Rigpa, Unani, and Homoeopathy drugs. Provisions relating to Ayurveda, Siddha, Sowa-Rigpa and Unani drugs are contained in Chapter IVA and Schedule-I of the Drugs and Cosmetics Act, 1940 and Rules 151-169, Schedules E(I), T & TA of the Drugs and Cosmetics Rules, 1945. Further, Second Schedule (4A) of the Drugs and Cosmetics Act, 1940 provides standards for Homoeopathic drugs and Rules 2dd, 30AA, 67 (C-H), 85 (A to I), 106-A, Schedule K, Schedule M-I of the Drugs Rules, 1945 pertain to Homoeopathic drugs. 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 the Good Manufacturing Practices (GMP) as per Schedule T & Schedule M-I of the Drugs Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

2. Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H) on behalf of Ministry of Ayush lays down the Formulary specifications and Pharmacopoeial Standards for ASU&H drugs, which serve as official compendia for ascertaining the Quality Control (identity, purity and strength) of ASU&H drugs, included herein, as per the Drugs & Cosmetics Act, 1940 and Rules 1945, thereunder and compliance to these quality standards are mandatory for ASU&H drugs being manufactured in India. Pharmacopoeias include

standards for raw materials for identity, purity, strength and quality to develop and standardize method of preparation, dosage forms, etc. PCIM&H acts as an appellate drug testing laboratory to receive the samples from Government agencies as per the Drugs & Cosmetics Act, 1940 & rules thereunder for ascertaining their quality.

3. Pharmacovigilance Centres for ASU&H drugs set up in different parts of the country under the Central Scheme of Ministry of Ayush are mandated to monitor and report the misleading advertisements to the respective State Regulatory Authorities. A three tier structure comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs) is established. All India Institute of Ayurveda (AIIA), New Delhi under Ministry of Ayush is the National Pharmacovigilance Co-ordination Centre (NPvCC) for the implementation of the National Pharmacovigilance program for ASU&H drugs. Objectionable advertisements are being reported to the respective State Licensing Authorities by PPvC at regular intervals.

4. Central Sector Scheme for Ayush Oushadhi Gunavatta evam Uttpadan Samvardhan Yojana (AOGUSY) has been implemented for the year 2021-2026. One of the components of this Scheme is strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.

5. An Ayush vertical has been created in Central Drugs Standard Control Organization (CDSCO) to strengthen regulatory measures ensuring safety and quality of Ayush drugs. As per the WHO Certificate of Pharmaceutical Product (CoPP) scheme, CDSCO issues CoPP to ASU drugs after examination of their application in consultation with Ministry of Ayush followed by joint inspection conducted by representatives from CDSCO, Ministry of Ayush and respective State Licensing Authority.

No reports of adulteration and rejection of Ayush consignments in the international market have been received in the Ministry.

(b) Ministry of Ayush is not running any collaborative programme with Government of Gujarat for identification of medicinal plants in Dang district.

(c) Rule 160 A to J of the Drugs Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratories for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurvedic, Siddha and Unani drugs. As on date, 34 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 108 laboratories are approved or licensed under the provisions of Drugs Rules, 1945 for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials.

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