### GOVERNMENT OF INDIA MINISTRY OF AYUSH

## RAJYA SABHA UNSTARRED QUESTION NO. 969 TO BE ANSWERED ON 09th DECEMBER 2025

#### Review of Ayush drug quality and research in Bihar

#### 969 Shri Akhilesh Prasad Singh:

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

- (a) whether Government has reviewed quality-control gaps in Ayush medicines produced or sold across the State of Bihar;
- (b) the steps taken to strengthen State-level Ayush drug-testing laboratories, pharmacovigilance units and certification systems; and
- (c) the plans to expand collaborative research on herbal formulations, medicinal plants and evidence-based Ayush therapies with universities in the State of Bihar?

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

(a) As per the Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945, enforcement of the legal provisions pertaining to quality control and issuance of drug license of Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy (ASU&H) drugs is vested with the State Drug Controllers/ State Licensing Authorities (SLAs) appointed by the concerned State/ Union Territory Government.

As per information received from State Bihar, the Drugs Control Administration, Department of Health, Bihar continuously monitor the Quality of drugs (Ayush) by performing inspection, sampling & testing of the marketed drugs in the state through its inspectorate staff. State Government has also notified a Government Analyst and a Drugs Testing Laboratory, Agamkuan, Patna for the test and analysis of Ayurvedic, Siddha, Unani and Homoeopathic Medicines.

- (b) Ministry of Ayush has implemented a Central Sector Scheme Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) since 2021-22 with total budget outlay of Rs. 122.00 crores for five years. The components of AOGUSY scheme are as follows -
- A. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.
- B. Pharmacovigilance of ASU&H drugs including surveillance of misleading advertisements.

- C. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.
- D. Support for development of standards and accreditation/certification of Ayush products & materials in collaboration with Bureau of Indian Standards (BIS), Quality Control of India (QCI) and other relevant scientific institutions and industrial R&D centres. Detailed guidelines of AOGUSY scheme are available at <a href="https://ayush.gov.in/images/Schemes/aoushdhi.pdf">https://ayush.gov.in/images/Schemes/aoushdhi.pdf</a>.

The Pharmacovigilance Program for ASU&H Drugs has been implemented under AOGUSY, which work through a three-tier network of a National Pharmacovigilance Centre (NPvCC), 05 Intermediary Pharmacovigilance Centers (IPvCs) and 97 Peripheral Pharmacovigilance Centers (PPvCs) established across the country. These centres are mandated to monitor and report misleading advertisements to the respective State Regulatory Authorities for suitable action against the defaulter.

Further Ministry of Ayush encourages following certifications of Ayush products as per details below: -

- The scheme for Certification of Pharmaceutical Product (CoPP) as per World Health Organization (WHO) guidelines is extended to Ayurvedic, Siddha and Unani (ASU) medicines. This scheme is administered by Central Drugs Standard Control Organization (CDSCO) and the certificate is granted on the basis of joint inspection of the applicant manufacturing unit by the representatives of CDSCO, Ministry of Ayush and the concerned State Licensing Authority.
- Quality Certifications Scheme is implemented by the Quality Council of India (QCI) for grant of Ayush mark viz. Ayush standard and Ayush premium marks to Ayurvedic, Siddha and Unani products on the basis of third party evaluation of quality in accordance with the status of compliance to GMP and WHO-GMP standards, respectively.
- (c) The Central Council for Research in Unani Medicine (CCRUM), an autonomous organization under Ministry of Ayush has signed a Memorandum of Understanding (MoU) with Government Tibbi College & Hospital Patna for collaborative research.

In addition, Central Council for Research in Ayurvedic Sciences (CCRAS) an autonomous organization under Ministry of Ayush has a Regional Ayurveda Research Institute (RARI) Patna as a peripheral institute of CCRAS located in Bihar. The institute undertakes research in infectious diseases and has been actively engaged in clinical trials, focusing on the efficacy, safety evaluation, and validation of various Ayurvedic formulations.

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