

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**RAJYA SABHA
UNSTARRED QUESTION NO. 965
TO BE ANSWERED ON 28.07.2026**

AYUSH drug quality and production enhancement scheme

965 Shri Harsh Mahajan:

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

- (a) the key provisions made under the AYUSH Drug Quality and Production Enhancement Scheme to ensure quality of AYUSH medicines and to enhance production capacity in the country;
- (b) the details of AYUSH drug manufacturing units established/upgraded under the said scheme across various States, particularly in Himachal Pradesh;
- (c) whether Government has developed any specific mechanism for standardisation, testing and certification of AYUSH medicines; and
- (d) if so, the details thereof?

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

(a) Ministry of Ayush is implementing a Central Sector Scheme namely Ayush Oushadhi Gunavatta evam Utpadan Samvardhan Yojana (AOGUSY) since 2021-22 with total budget outlay of Rs. 122.00 crores for five years. The components of scheme are as follows: -

- i. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards- under this component support is provided to Ayush drug manufacturers (Government and Private) for strengthening and upgradation of Ayush pharmacies and for Drug Testing Laboratories (DTLs) to achieve higher standards like WHO-GMP & NABL respectively.
- ii. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs- Ayush vertical in Central Drugs Standards Control Organization (CDSCO) and State Ayush Directorate/State Drug Controller of Ayush drugs are financially supported under AOGUSY Scheme for conducting training and capacity building programs.

- iii. Pharmacovigilance of ASU&H drugs including surveillance of misleading advertisements- The Pharmacovigilance Program for ASSU&H drugs under AOGUSY scheme functions through a nationwide three-tier network comprising 01 National Pharmacovigilance Co-ordination Centre (NPvCC), 05 Intermediary Pharmacovigilance Centres (IPvCs), and 97 Peripheral Pharmacovigilance Centres (PPvCs) established across the country. These centres are mandated to monitor suspected adverse drug reactions and report the misleading advertisements to the respective State Regulatory Authorities for suitable action against the defaulter(s). Further, through this program various stakeholders across the country are sensitised towards the quality of medicines, posologies and other drug-related issues.
- iv. 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.

(b) Till date, 18 Ayush pharmacies and 07 Ayush DTLs have been supported financially under this scheme across the country. The State/UT-wise details of Ayush drug manufacturing units and Drug Testing Laboratories (DTLs) supported for upgradation under the component 'Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards' of AOGUSY scheme is furnished at Annexure. However, till date, no AYUSH drug manufacturing unit or Drug Testing Laboratory (DTL) has been supported for establishment or upgradation under the AOGUSY scheme in Himachal Pradesh.

(c) & (d) The Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a subordinate organization under Ministry of Ayush, develops pharmacopoeial standards and formulary specifications for Ayush drugs, which serve as the official compendia for determining their identity, purity, and strength. Compliance with these standards is mandatory under the Drugs and Cosmetics Act, 1940 and the Rules made thereunder. PCIM&H also functions as the Appellate Drug Testing Laboratory for Ayush drugs and conducts regular capacity-building programmes for Drug Regulatory Authorities, Drug Analysts, and other stakeholders on standardization, quality control, and testing methodologies to strengthen the quality assurance system for Ayush drugs.

The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 have exclusive regulatory provisions for Ayurveda, Siddha, Sowa-Rigpa, Unani and Homoeopathy (ASSU&H) 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 and Schedule M-I of the Drugs Rules, 1945 for Ayurvedic, Siddha, Sowa-rigpa, Unani and Homeopathy drugs respectively and to follow the quality standards of drugs as prescribed in the respective pharmacopoeia.

Drug Inspectors collect medicine samples regularly from manufacturing firms or retail shops within their jurisdiction and send them to Drug Testing Laboratory under Drug Control department for quality testing and if any sample is found to be 'Not of Standard Quality', appropriate action is initiated such as preventing the sale of the medicines from the market and appropriate legal actions as per Drugs and Cosmetics Act, 1940 and Rules made thereunder. There are 34 Drug Testing Laboratories available in State/UTs for testing of the Legal Samples drawn by the Drug Inspectors of concerned State/UTs.

Further, the Ministry of Ayush has undertaken the following initiatives to promote quality assurance and certification of Ayush products:

- Ayush Vertical in CDSCO facilitates the issuance of the World Health Organization Certificate of Pharmaceutical Product (WHO-CoPP) for eligible Ayush drugs through joint inspections with State/UT Licensing Authorities.
- Ayush Standard Mark and Ayush Premium Mark are awarded to Ayush Drugs by Quality Council of India (QCI) based on third-party assessment of compliance with prescribed national and international quality standards.
- Ayush Quality Mark Programme was launched by the Ministry of Ayush to strengthen quality assurance, enhance consumer confidence, and improve the Global recognition and competitiveness of Ayush products and services.

Annexure

The State/UT-wise details of AYUSH drug manufacturing units and Drug Testing Laboratories (DTLs) supported for upgradation under the component of Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards of AOGUSY scheme till date, including Himachal Pradesh, are as follows-

S. No.	State	Pharmacy / DTL	Name of the Firm/Organisation
1	Mizoram	DTL	State Govt. DTL
2	Maharashtra	Pharmacy	Inducare Pharma Pvt. Ltd. Pune
3	Maharashtra	Pharmacy	Ayurchem Private Ltd. Maharashtra
4	Maharashtra	Pharmacy	Phytovedic India Pvt. Ltd. Maharashtra
5	Kerala	Pharmacy	Visesh Ayurvedic Pvt. Ltd Pharmacy Kerala
6	Uttar Pradesh	Pharmacy	Amar Pharmaceuticals and Labs (I) Pvt. Ltd. U.P
7	Uttar Pradesh	DTL	Amar Pharmaceuticals and Labs (I) Pvt. Ltd. U.P (DTL)
8	Madhya Pradesh	Pharmacy	Shree Baidyanath Ayurved Bhawan Pvt. Ltd., Madhya Pradesh
9	Kerala	Pharmacy	Kollam District Ayurveda Oushdha Nirmana Vyavasaya Co-operative Society Ltd., Kerala
10	Tripura	DTL	State Govt. DTL
11	Jammu & Kashmir	DTL	State Govt. DTL
12	Kerala	Pharmacy	Sitaram Ayurveda Pvt. Ltd., Thrissur, Kerala
13	Kerala	Pharmacy	Pankajakasthuri Herbals India Private Limited, Poovachal, Kerala
14	Rajasthan	Pharmacy	BJain Pharmaceuticals Private Limited, Alwar, Rajasthan
15	Assam	Pharmacy	Assam Ayurvedic Products, Guwahati, Assam (PSU)
16	Jammu & Kashmir	Pharmacy	Govt. Pharmacy, Jammu & Kashmir
17	Gujarat	Pharmacy	State Pharmacy, Rajpipla, Gujarat
18	Tamil Nadu	DTL	State Govt. Drug Testing Laboratory, Tamil Nadu
19	Arunachal Pradesh	Pharmacy	State Pharmacy, Arunachal Pradesh
20	Arunachal Pradesh	DTL	State Drug Testing Laboratory, Arunachal Pradesh
21	Tamil Nadu	Pharmacy	State Govt. Pharmacy, Tamil Nadu Medicinal Plant Farms & Herbal Medicine Corporation Limited (TAMPCOL), Tamil Nadu
22	Punjab	Pharmacy	Shree Dhanwantari Herbals Pvt. Ltd.
23	Kerala	Pharmacy	The Pharmaceutical Corporation (IM) Kerala Ltd., Kuttanellur P.O., Thrissur
24	Madhya Pradesh	Pharmacy	State Govt. Pharmacy, Gwalior
25	Madhya Pradesh	DTL	State Govt. Drug Testing Laboratory, Madhya Pradesh