

GOVERNMENT OF INDIA
MINISTRY OF AYUSH
LOK SABHA
UNSTARRED QUESTION NO. 3334
TO BE ANSWERED ON 08th AUGUST 2025

“AYUSH Aushadhi Gunvatta Evam Utpadan Samvardhan”

3334. Dr. Rajkumar Sangwan:

Will the Minister of Ayush be pleased to state:

- (a) the details of target set by the Government under the AYUSH Aushadhi Gunvatta Evam Utpadan Samvardhan Yojana and the achievements made as a result thereof during the last five years ;
- (b) whether the Government has any action plan or set any target to promote the export of traditional major medicines and health improvement products through the AYUSH Aushadhi Gunvatta Evam Utpadan Samvardhan Yojana;
- (c) if so, the details thereof along with achievements made during the last five years;
- (d) whether the Government has taken any measures for effective quality control and safety monitoring of AYUSH medicines; and
- (e) if so, the details thereof?

ANSWER

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

(a) to (c) In the year 2021, Ministry of Ayush has implemented a Central Sector Scheme- Ayush Oushadhi Gunavatta Evam Utpadan Samvardhan Yojana (AOGUSY), with total Budget allocation of Rs. 122.00 crores for five years. The objectives of the Scheme are as under;

- i. To enhance India's manufacturing capabilities and exports of traditional medicines and health promotion products under the initiative of Atmanirbhar Bharat.

- ii. To facilitate adequate infrastructural & technological upgradation and institutional activities in public and private sector for standardization, quality manufacturing and analytical testing of Ayush drugs & materials.
- iii. To strengthen regulatory frameworks at Central and State level for effective quality control, safety monitoring and surveillance of misleading advertisements of Ayush drugs.
- iv. To encourage building up synergies, collaborations and convergent approaches for promoting standards and quality of Ayush drugs & materials.

2. The components of Central Sector Scheme- Ayush Oushadhi Gunavatta Evam Utpadan Samvardhan Yojana (AOGUSY) are as follows:

- i. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.
- ii. Pharmacovigilance of Ayurveda, Siddha, Unani, and Homoeopathy (ASU & H) Drugs, including surveillance of misleading advertisements.
- iii. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.
- 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.

3. Under first component of AOGUSY Scheme, Ministry of Ayush has financially supported 16 ASU & H pharmacies and 06 ASU&H drug testing laboratories till date to achieve higher standards. The details of Grant-in-Aid are attached as **Annexure-I**.

4. Under second component of AOGUSY Scheme, Ministry of Ayush has implemented a Pharmacovigilance Program for ASU & H Drugs. This pharmacovigilance program is working through a three-tier network pharmacovigilance centers distributed throughout the country with one National Pharmacovigilance Coordination Center (NPvCC), 5-Intermediary Pharmacovigilance Centers (IPvC) & 97 Peripheral Pharmacovigilance Centers (PPvC). 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 Ayurveda, Siddha, Unani & Homoeopathy drugs. These centres are mandated to monitor and report the misleading advertisements to the respective State Regulatory Authorities for suitable action against the defaulter(s). Also, the program is regularly

reporting Suspected Adverse Drug Reactions for ASU &H drugs. The objectives of the program are as below:-

- To improve patient healthcare and safety in relation to the use of medicines.
- To develop the culture of documenting adverse effects.
- To promote understanding, education and training in Pharmacovigilance and its communication to healthcare professionals and the public.
- Surveillance of misleading advertisements appearing in the print and electronic media.

5. The achievements made under the Pharmacovigilance Program in the last five years are attached as **Annexure-II**.

6. Under third component of AOGUSY Scheme, three trainings has been conducted for Ayush drug regulators, industry personnel and other stake holders.

(d) & (e) The details of measures taken by Government for effective quality control and safety monitoring of AYUSH medicines are as follows:-

1. The Drugs & Cosmetics Act, 1940 and Drugs Rules, 1945 have exclusive regulatory provisions for Ayurvedic, Siddha, Sowa-Rigpa, Unani, and Homoeopathy drugs. It is mandatory for the manufacturers to adhere to the prescribed requirements in compliance with the Good Manufacturing Practices (GMP) as per Schedule T & Schedule M-I of Drugs Rules, 1945 including safety, effectiveness and quality standards of drugs given in the respective pharmacopoeia.
2. Drug Inspectors collect medicine samples regularly from manufacturing firms or 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 products from the market

and appropriate legal actions as per Drugs and Cosmetics Act 1940 and Rules made thereunder

3. Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), subordinate office under 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 thereunder, the compliance to this 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 has been published.
4. PCIM&H also acts as the Central Drugs Laboratory for Indian Medicine and Homoeopathy for the purpose of testing or analysis of ASU&H Drugs. Further, it imparts Capacity Building Trainings at regular interval for standardization/quality control/ testing or analysis of ASU&H drugs to Drug Regulatory Authorities, State Drug Testing Laboratories (Drug Analyst) and other stakeholders on quality control of ASU&H drugs on laboratory techniques and methods used to maintain the quality of ASU&H drugs.
5. Drug Testing Laboratories are being recognised under Rule 160 A to J of the Drugs Rules, 1945 for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs. As on date, 108 private laboratories are approved or licensed under the provisions of Drugs Rules, 1945 for manufacturers. 34 Drug Testing Laboratories of State/UTs are testing quality of Ayurvedic, Siddha, Sowa-Rigpa, Unani and Homoeopathy drugs and raw materials for legal samples.

6. The Pharmacovigilance Program for Ayurvedic, Siddha, Unani and Homoeopathy (ASU & H) Drugs monitor and report misleading advertisements. Also, the program is regularly reporting Suspected Adverse Drug Reactions for ASU &H drugs.
7. Ministry of Ayush has developed and launched an IT enabled online portal “Ayush Suraksha” for Ayush Health care professionals and public to track the reported misleading advertisements (MLAs)/Objectionable Advertisements (OAs) and Adverse Drug Reactions (ADRs) on 30th May 2025.

Annexure-I

The details of the incentives given for strengthening and upgradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards during the last five years are as follows:

S. No.	F.Y.	State	Component	Pharmacy/ DTL	Particulars	Amount released
1	2021-22	Mizoram	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	DTL	State Govt. of Mizoram	Rs. 1,800,000
2	2022-23	Pune	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	Pharmacy	Inducare Pharma Pvt.Ltd. Pune	Rs. 30,000,000
3		Maharashtra		Pharmacy	Ayurchem Private Ltd. Maharashtra.	Rs. 26,900,000
4		Maharashtra		Pharmacy	Phytovedic India Pvt. Ltd. Maharashtra	Rs. 21,461,000
5		Kerala		Pharmacy	Visesh Ayurvedic Pvt. Ltd Pharmacy Kerala.	Rs. 19,156,000
6		Uttar Pradesh		Pharmacy	Amar Pharmaceuticals and labs (I) Pvt. Ltd. U.P	Rs. 14,343,000
7		Uttar Pradesh		DTL	Amar Pharmaceuticals and labs (I) Pvt. Ltd. U.P (DTL)	Rs. 7,767,000
8		Madhya Pradesh		Pharmacy	Shree Baidyanath Ayurved Bhawan Pvt. Ltd, Madhya Pradesh	Rs. 20,892,000
9		Kerala		Pharmacy	Kollam District Ayurveda Oushdha Nirmana Vyavasaya Co-operative Society Ltd, Kerela	Rs. 6,429,000
10	2023-24	Tripura	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	DTL	State Govt. of Tripura	Rs. 7,668,000

11		Madhya Pradesh	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	Pharmacy	Shree Baidyanath Ayurved Bhawan Pvt. Ltd, Madhya Pradesh	Rs. 9,108,000
12		Jammu & Kashmir	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	DTL	State Govt. J&K	Rs. 8,629,500
13		Kerala	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	Pharmacy	Sitaram Ayurveda Pvt. Ltd, Thrissur, Kerala.	Rs. 5,000,000
14		Kerala		Pharmacy	Pankajakasthuri Herbals India Private Limited, Poovachal, Kerala	Rs. 5,000,000
15		Rajasthan		Pharmacy	BJain Pharmaceuticals Private Limited, Alwar, Rajasthan	Rs. 5,000,000
16		Assam		Pharmacy	Assam Ayurvedic Products, Guwahati, Assam (PSU)	Rs. 4,559,519
17		Jammu & Kashmir		Pharmacy	Govt. Pharmacy, Jammu & Kashmir	Rs. 10,500,000
18		Gujarat		Pharmacy	State Pharmacy, Rajpipla, Gujarat	Rs. 4,420,248
19		Mizoram		DTL	State Govt. Drug Testing Laboratory, Mizoram	Rs. 6,720,884
20		Tamil Nadu		DTL	State Govt. Drug Testing Laboratory, Tamil Nadu	Rs. 2,000,000
21		Arunachal Pradesh		Pharmacy	State Pharmacy, Arunachal Pradesh	Rs. 6,702,164
22		Arunachal Pradesh		DTL	State Drug Testing Laboratory , Arunachal Pradesh	Rs. 1,799,813
23	2024-25	Arunachal Pradesh	Strengthening and up-gradation of Ayush Pharmacies	Pharmacy	State Pharmacy, Arunachal Pradesh	Rs. 7,042,077

24	Arunachal Pradesh	and Drug Testing Laboratories to achieve higher standards	DTL	State Drug Testing Laboratory , Arunachal Pradesh	Rs. 1,724,400
25	Kerala		Pharmacy	Pankajakasthuri Herbals India Private Limited, Poovachal, Kerala	Rs. 4,432,807
26	Tamil Nadu	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	DTL	State Govt. Drug Testing Laboratory, Tamil Nadu	Rs. 5,100,000
27	Rajasthan		Pharmacy	BJain Pharmaceuticals Private Limited, Alwar, Rajasthan	Rs. 14,454,189
28	Mizoram		DTL	State Govt. Drug Testing Laboratory, Mizoram	Rs. 3,940,500
29	Tamil Nadu		DTL	State Govt. Drug Testing Laboratory, Tamil Nadu	Rs. 4,157,062
30	Gujarat		Pharmacy	State Pharmacy, Rajpipla, Gujarat	Rs. 20,000,000
31	Mizoram	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	DTL	State Govt. Drug Testing Laboratory, Mizoram	Rs. 1,800,000
32	Tamil Nadu	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	Pharmacy	State Govt. Pharmacy, Tamil Nadu Medicinal Plant Farms & Herbal Medicine Corporation Limited (TAMPCOL), Tamil Nadu	Rs. 4,500,000

33		Arunanchal Pradesh	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	Pharmacy	State Pharmacy, Arunanchal Pradesh	Rs. 3,108,000
34	2025-26	Punjab	Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards	Pharmacy	Shree Dhanwantari Herbals Pvt. Ltd.	28,500,000
					Total	Rs. 324,615,163

Annexure-II

The achievements made under the Pharmacovigilance Program in the last five years are as follow:

- To enhance understanding and promote effective communication regarding pharmacovigilance in the ASU&H sector, a series of awareness programs have been conducted over the past five years. These initiatives aimed at sensitizing stakeholders-including practitioners, manufacturers, healthcare professionals, and the general public-towards the importance of drug safety monitoring and adverse event reporting. The details of such programs conducted during the last five years are as follows:

Year	Awareness Program	Beneficiaries
2021	118	14659
2022	292	23510
2023	586	43396
2024	1065	105148
2025 (June 2025)	692	66255
Total	2753	252968

- Reporting of Suspected Adverse Drug Reactions (ADRs) is one of the major components of this program. Reported such suspected case reports in last five years as below:

Year	Suspected ADR's
2021	360
2022	324
2023	420
2024	521
2025 (June 2025)	382
Total	2007

- Pharmacovigilance Program also aims at keeping a surveillance on misleading advertisements for ASU & H drugs, details of last five years as below:

Year	Misleading Advertisements
2021	8144 + 43 (COVID)
2022	7367 + 4 (COVID)
2023	7771
2024	10161
2025 (June 2025)	6650
Total	40140