

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**LOK SABHA
UNSTARRED QUESTION NO. 3506
TO BE ANSWERED ON 21st March 2025**

“Export of Traditional Medicines and Health Products”

3506. Dr. Sambit Patra:

Will the Minister of Ayush be pleased to state:

- (a) the details of the targets set by the Government under AYUSH Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana and the achievements made thereunder during the last five years;
- (b) whether the Government has implemented any action plan to enhance the export of traditional medicines and healthcare products through Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana and if so, the details thereof;
- (c) whether the Government has set any targets for export of traditional medicines and healthcare products through Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana;
- (d) if so, the details of the targets set and achievements made thereunder during the last three years;
- (e) whether the Government has taken any measures for effective quality control, safety monitoring and surveillance of misleading advertisements of AYUSH medicines; and
- (f) if so, the details thereof?

ANSWER

**THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH
(SHRI PRATAPRAOJADHAV)**

- (a)** In the year 2021, Ministry of Ayush has implemented a Central Sector Scheme- Ayush Oushadhi Gunavatta Evam Utpadan Samvardhan Yojana (AOGUSY), the total Budget

allocation to this scheme is Rs. 122.00 Crores for five years. The components of AOGUSY scheme are as follows:

1. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.
2. Pharmacovigilance of ASU&H drugs including surveillance of misleading advertisements.
3. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.
4. 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.

The first component of the Scheme is Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards. This component is intended to increase the standards of Ayurveda, Siddha, Unani and Homoeopathy(ASU&H) Pharmacies and Drug Testing Laboratories (DTL) to World Health Organisation(WHO)- Good Manufacturing Practices(GMP) and National Accreditation Board for Testing and Calibration Laboratories(NABL) levels, respectively. Till date, 20 ASU&H pharmacies and 12 ASU&H drug testing laboratories have been supported financially under this scheme.

The second component of the Scheme deals with Pharmacovigilance Program for ASU&H Drugs, working through a three-tier network of a National Pharmacovigilance Centre (NPvCC), 5 Intermediary Pharmacovigilance Centers (IPvCs) and 99 Peripheral Pharmacovigilance Centers (PPvCs) across the country. In this regard, during the last five years (till February 2025), a total of 35928 misleading advertisements related to Ayush drugs have been identified, which are reported 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, wherein 1762 such suspected signals have been reported till date. Further, towards sensitizing various healthcare professional cohorts, 2324 awareness programs have been conducted with 213673 beneficiaries.

Under the third component of the Scheme- Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs, three training programmes have been conducted for Ayush drug regulators,

industry personnel and other stake holders in the different zones of the country, which are South Zone, North-Eastern states and Central Zone, till date.

(b) to (d) The action plan implemented by the Government to enhance the export of traditional medicines and healthcare products through Ayush Oushadhi Gunvatta Evam Utpadan Samvardhan Yojana(AOGUSY) is as follows:-

The first component of the Scheme- Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards is intended to increase the standards of ASU&H Pharmacies and DTLs to WHO-GMP and NABL levels respectively. The funding pattern details are as follows-

1. The State Govt./U.T.'s ASU&H Pharmacies/State Govt. ASU&H Cooperatives, State Govt. ASU&H PSUs are funded up to Rs. 6.00 crore for strengthening infrastructure & technology up-gradation and meeting associated recurring costs for upgrading pharmacy in terms of technology used and quantum of production whereas, the Private ASU&H Pharmacies are supported with 50% of the project cost limited to Rs. 3.00 crore for equipment, machinery and scientific instruments to achieve higher standards of GMP (like WHO-GMP, cGMP, EU-GMP) for obtaining WHO-GMP certification within 2 and 1/2 years from the date of first disbursement of Grant-in-Aid.
2. The State/U.T. Govt ASU&H Drug Testing Laboratories, Government and Research Councils laboratories are funded upto Rs. 3.00 crore for strengthening infrastructure & technology up-gradation to acquire NABL accreditation and meeting recurring costs of chemicals & reagents, consumables and technical manpower whereas, the Private ASU&H Drug Testing Laboratories/in house Quality Control Lab of GMP certified ASU&H manufacturing units are supported with 50% of the project cost limited to Rs. 1.50 crore for acquiring scientific equipment and instruments for NABL accreditation, in order to follow NABL Guidelines & get accredited as 'NABL' in stipulated time-frame.

Till date, 20 ASU & H pharmacies and 12 ASU&H drug testing laboratories have been supported financially. Further, for release of Grand-in-aid All India Institute of Ayurveda, New Delhi, AIIA is designated as Central Nodal Agency. The details of Grant-in-Aid are annexed as **Annexure-I.**

(e) and (f) Yes, the measures taken for effective quality control, safety monitoring and surveillance of misleading advertisements of Ayush medicines are as follows;

1. As prescribed in Drugs and Cosmetics Act 1940 and Rules made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathy drugs, is vested with the State Drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government. Rule 158-B in the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic, Siddha, Unani medicines and Rule 85 (A to I) in the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathy medicines. 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. Drug Inspectors collect medicine samples regularly from industries and Markets and sent it to State Drug Testing Laboratory for quality testing and take further necessary action(s) on the basis of such tests reports as per Drugs and Cosmetics Act 1940 and Rules made thereunder .

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 the ASU&H drugs, included herein, as per Drugs & Cosmetics Act, 1940 and Rules 1945 and compliance to these quality standards are mandatory for manufacturing, sale and stock of ASU&H drugs in India. The quality parameters included in the Pharmacopoeias and Formularies of Ayurveda, Siddha, Unani & Homoeopathic (ASU&H) drugs prescribing mandatory regulatory standards have been identified to align the parameters prescribed by WHO/other major pharmacopoeias prevalent worldwide. Implementation of these pharmacopoeial standards ensures optimum quality standards in terms of identity, purity and strength of ASU&H drugs.

3. The Pharmacovigilance Program for ASU & H Drugs has been implemented under Central Sector Scheme Ayush Oushadhi Gunavatta Evam Utpadan Samvardhan Yojana (AOGUSY), which work through a three-tier network of a National Pharmacovigilance Centre (NPvCC), Five Intermediary Pharmacovigilance Centers (IPvCs) and 99 Peripheral Pharmacovigilance Centers

(PPvCs) established across the country. 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). Under the Pharmacovigilance program, as of February 2025, a total of 35928 misleading advertisements related to Ayush drugs have been identified. Also, the program is regularly reporting Suspected Adverse Drug Reactions for ASU &H drugs, wherein 1762 such suspected signals have been reported till date. Further, towards sensitizing various healthcare professional cohorts, 2324 awareness programs have been conducted with 213673 beneficiaries. Details are annexed as **Annexure II**.

Annexure-I

Details of Funds Released under AOGUSY Central Sector Scheme

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
				Total	Rs. 293,007,163

Annexure -II

Year	Misleading Advertisements	Suspected ADR's
2021	8144 + 43 (COVID)	360
2022	7367 + 4 (COVID)	324
2023	7771	420
2024	10161	521
2025 (Feb 2025)	2438	137
Total	35928	1762

Year	Awareness Program	Beneficiaries
2021	118	14659
2022	292	23510
2023	586	43396
2024	1065	105148
2025 (Feb 2025)	263	26960
Total	2324	213673