GOVERNMENT OF INDIA
MINISTRY OF AYUSH
LOK SABHA
STARRED QUESTION NO. 297
TO BE ANSWERED ON 08th AUGUST 2025

"AYUSH Drugs in Rural Markets"

297. Adv Priya Saroj:

Will the Minister of AYUSH be pleased to state:

(a) the existing regulatory framework and mechanisms for ensuring the quality, safety and efficacy of AYUSH drugs and products available in rural markets across the country and the number of drug testing laboratories dedicated to AYUSH products, State/UT-wise;
(b) the total number of cases of substandard, misbranded and adulterated AYUSH drugs reported from rural areas in the last three financial years, State-wise and the punitive actions taken against the manufacturers and distributors of such drugs;
(c) the details of initiatives taken by the Government to strengthen pharmacovigilance of AYUSH drugs, especially in rural areas; and
(d) the measures being adopted by the Government to promote Good Manufacturing Practices (GMP) among small and medium-scale AYUSH drug manufacturers operating in rural and semi-urban areas and the details of financial or technical assistance provided for their compliance?

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH

(SHRI PRATAPRAO JADHAV)

(a) to (d) A statement is laid on the Table of the House.

THE STATEMENT REFERRED TO IN REPLY TO LOK SABHA STARRED QUESTION NO. 297 FOR 08th AUGUST 2025.

(a) The details of existing regulatory framework and mechanisms for ensuring the quality, safety and efficacy of Ayush drugs and products available in rural markets across the country and the number of drug testing laboratories dedicated to Ayush products, State/UT-wise 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. Provisions relating to Ayurveda, Siddha and Unani Drugs are contained in Chapter IVA and Schedule- I of the Drugs and Cosmetics Act, 1940 and in Rules 151 to 169, Schedules E(I), T & TA of the Drugs 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 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 sale 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. The details of number of drug testing laboratories dedicated to Ayush products, State/UT-wise are available at Annexure-I.

6. Ministry of Ayush has implemented Central Sector Scheme Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) to support Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards under one of the components.

7. Pharmacovigilance Program for Ayurveda, Siddha, Unani, and Homoeopathy (ASU & H) Drugs is one of the components under the AOGUSY Scheme of Ministry of Ayush. This is established with an objective of improving patient healthcare and safety in relation to the use of medicines, developing culture of documenting adverse effects, promoting education and training in Pharmacovigilance, and surveillance of misleading advertisements appearing in the print and electronic media.

(b) As per the information received from states/UTs governments, the details of the total number of cases of substandard, misbranded and adulterated Ayush drugs reported from rural areas in the last three financial years, State-wise and the punitive actions taken against the manufacturers and distributors of such drugs are attached at **Annexure-II.**

(c) And (d) The details of initiatives taken by the Government to strengthen pharmacovigilance of Ayush drugs, especially in rural areas; and the measures being adopted by the Government to promote Good Manufacturing Practices (GMP) among small and medium-scale Ayush drug manufacturers operating in rural and semi-urban areas and the details of financial or technical assistance provided for their compliance are as follows: -

1. Ministry of Ayush has implemented Central Sector Scheme Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY). The total financial allocation to this scheme is 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 https://ayush.gov.in/resources/pdf/schemes/aoushdhi.pdf

2. The Pharmacovigilance Program for Ayurvedic, Siddha, Unani and Homoeopathy (ASU & H) Drugs has been implemented under Central Sector Scheme Ayush Oushadhi Gunavatta Evam Uttpadan Samvardhan Yojana (AOGUSY), which work through a three-tier network of a National Pharmacovigilance Centre (NPvCC), Five 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. Objectives of this program is to keep vigilance over Ayush drugs and to reduce misleading advertisements to ensure the consumer protection and prevent the dissemination of unverified claims by Ayush product manufacturers.

3. To strengthen pharmacovigilance of Ayush drugs, regular awareness programs have been conducted throughout the nation under the pharmacovigilance program for ASU & H drugs for practitioners, healthcare workers and other different cohort including general public to disseminate the awareness regarding patient safety. Till date 3464 awareness programs have been conducted with 328709 beneficiaries across the country. Details are available as **Annexure III.**

4. 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.

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

   • An Ayush vertical has been created in Central Drugs Standard Control Organization (CDSCO) to strengthen regulatory measures ensuring safety and quality of Ayush drugs. Further, CDSCO issues WHO Certificate of Pharmaceutical Product (WHO-CoPP) to Ayush drugs having compliance to such standards.

   • Quality Certifications Scheme implemented by the Quality Council of India (QCI) for grant of AYUSH standard and premium mark to Ayurvedic, Siddha and Unani products on the basis of third-party evaluation of quality in accordance with the status of compliance to domestic and international standards.

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Annexure-I

The details of number of drug testing laboratories dedicated to AYUSH products, State/UT-wise are as follows: -

S. No.	State/UT	Government/UTs drug testing laboratories	Private drug testing laboratories approved under Rule 160 A to J of Drugs Rules 1945.
1.	Andhra Pradesh	01	00
2.	Arunanchal Pradesh	01	00
3.	Assam	01	00
4.	Bihar	01	00
5.	Chhattisgarh	01	00
6.	Gujarat	01	06
7.	Haryana	01	09
8.	Himachal Pradesh	01	03
9.	Jammu and Kashmir	01	00
10.	Jharkhand	01	00
11.	Karnataka	01	09
12.	Kerala	02	09
13.	Madhya Pradesh	01	06
14.	Maharashtra	02	13
15.	Manipur	01	00
16.	Mizoram	01	00
17.	Meghlaya	01	00
18.	Nagaland	01	00
19.	Odisha	02	04
20.	Puducherry	01	00
21.	Punjab	01	02
22.	Rajasthan	01	10
23.	Sikkim	01	00
24.	Tamilnadu	01	12

25.	Telangana	02	01
26.	Tripura	01	00
27.	Uttar Pradesh	02	05
28.	Uttarakhand	01	05
29.	West Bengal	01	01
30.	Delhi	00	13

Annexure-II

State/UT wise details of the total number of cases of substandard, misbranded and adulterated AYUSH drugs reported from rural areas in the last three financial years, State-wise and the punitive actions taken against the manufacturers and distributors of such drugs are as follows:

<table>
<tr><th>S.No.</th><th>State</th><th>Replies</th></tr>
<tr><td>1.</td><td>Kerala</td><td>
<table>
<tr><th>Serial Number</th><th>Name of substandard medicine</th><th>Name of manufacturer</th><th>Details of legal action</th></tr>
<tr><td>1</td><td>Mustharishtam
AA 02/22</td><td>M/S Valluwanad Ayurveda Oushadhasala, Keralassery</td><td>Product suspended for one month</td></tr>
<tr><td>2</td><td>Hinguvachaadi Gulika
XBGD</td><td>M/S Nagarjuna Herbal Concentrates Ltd. Kalayanthanni, Thodupuzha</td><td>Departmental action- Suspension of production for 30 days</td></tr>
<tr><td>3</td><td>Mustharishtam</td><td>M/S Sidda Herbal Products, Porathissery, Irinjalakkuda,Thrissur</td><td>Product suspended for one month</td></tr>
<tr><td>5</td><td>Amruthrotharam Kashayam</td><td>Itoozhi vaidhyasala ,Mayyil,Kannur</td><td>Product suspended for one month</td></tr>
<tr><td>6</td><td>Dhanwantharam Kashayam</td><td>Itoozhi vaidhyasala ,Mayyil,Kannur</td><td>Final complaint filed before the court on 4/10/2024</td></tr>
<tr><td>7</td><td>Abhayarishtam</td><td>M/s Bala Herbals, Industrial Estate, Karunagappally, Kollam</td><td>Final Complaint Filed before Honourable JFM Court-Karunagappally
Case No ST 585/23</td></tr>
</table>
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		8	Dasamoolarishtam	M/s PM Pharmacy Kollam	Product suspended for one month
		9	Haridrakhandam	Chaithanya Ayurveda Pharmacy Vadakara,Kozhikode	Product suspended for one month
		10	Gee Pee Choornam	Sun Ayurvedic Medicines ,Ponnani,Malappuram	Took departmental action
		11	Ashokarishtam Batch No 01/2025	Jayalekshmi Pharma Mynagapally,Kollam	Sent showcause notice and stopped the sale of the product
		12	Dasamularishtam	M/s Vaidyasala Veettil Oushadhasala, Elamadu PO, Kollam	Sent showcause notice and stopped the sale of the product
		13	Amrutharishtam	M/s Vaidyasala Veettil Oushadhasala, Elamadu PO, Kollam	Sent showcause notice and stopped the sale of the product
		14	Asokarishtam	Sakthi Ayruveda Pharmaceuticals, Thiruvananthapuram	Final complaint is being prepared for filing before the court.
		15	Balarishtam	Sakthi Ayruveda Pharmaceuticals,	Final complaint is being prepared for

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<tr><td></td><td></td><td>Thiruvananthapuram</td><td>filing before the court.</td></tr>
<tr><td>16</td><td>Amrutharishtam</td><td>Sakthi Ayruveda Pharmaceuticals, Thiruvananthapuram</td><td>Final complaint is being prepared for filing before the court.</td></tr>
</table>
</td></tr>
<tr><td>2.</td><td>Jharkhand</td><td>
<table>
<tr><th>Sl.</th><th>Name of Product</th><th>Manufacturer</th><th>Action</th></tr>
<tr><td>1.</td><td>HELLO-Jiv</td><td>M/s Yuvnam Private Limited, Gutuwa, Ranchi</td><td>Product approval cancelled</td></tr>
<tr><td>2.</td><td>REPL Orthovit Capsule</td><td>Renovision Export Pvt. Ltd UNIT-II Bhuyandih, Kamidih, P.O. Chilgu, PS:- Chandil, Dist: Saraikela-Kharsawan-832401</td><td>Case Filed</td></tr>
<tr><td>3.</td><td>Menstrual Pain Min 30ml</td><td>Bharti Pharma, C-39, Phase2, Industries Area, Adityapur-831013</td><td>Product suspended for 60 days</td></tr>
<tr><td>4.</td><td>Liv Drops 30ml</td><td>Bharti Pharma, C-39, Phase2, Industries Area, Adityapur-831013</td><td>Product suspended for 60 days</td></tr>
<tr><td>5.</td><td>Urginia Tincture IP 66</td><td>M/s Moxie Pharmaceuticals Pvt. Ltd., Shed No.- B 12 & 13, Jasidih Industrial Area, Jasidih, Deoghar-814142</td><td>Product Cancel/Removed from approved products list</td></tr>
</table>
</td></tr>
<tr><td>3.</td><td>Tripura</td><td>
<table>
<tr><th>Year wise report</th><th>Misbranded Ayush medicines</th><th>Not of standard Ayush medicines</th></tr>
<tr><td>2022-2023</td><td>62</td><td>03</td></tr>
<tr><td>2023-2024</td><td>07</td><td>-</td></tr>
<tr><td>2024-2025</td><td>36</td><td>-</td></tr>
<tr><td>2025-till date</td><td>-</td><td>01</td></tr>
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<tr><td>4.</td><td>Goa</td><td>
<table>
<tr><td></td><td>Product Name</td><td>Mfg by</td><td>Action</td></tr>
<tr><td>01 case of NSQ drug reported</td><td>Avipattikar Churna (Tablets), B.N: HCT-21, M/D: 12/2021, E/D: 11/2024,:</td><td>M/s. Karnani Pharmaceuticals (P) Ltd; Fact: F-67, Industrial Area, Bhiwadi - 302019 (RAJ), does not conform to Description.</td><td>suspended the manufacturing license of the firm M/s. Karnani Pharmaceuticals (P) Ltd for the period of six months.

Showcause Notice was issued to Hospital Pharmacy, North Goa District Hospital, (Asilo Hospital), Mapusa Goa, from where the sample was drawn.</td></tr>
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<tr><td>5.</td><td>Maharashtra</td><td>The total number of cases of substandard, misbranded and adulterated AYUSH drugs reported from Maharashtra State in the last three financial years are as follows: -
<table>
<tr><td>Period</td><td>01/04/2022 to 31/03/2023</td><td>01/04/2023 to 31/03/2024</td><td>01/04/2024 to 31/03/2025</td><td>01/04/2025 to 30/06/2025</td></tr>
<tr><td>Ayurvedic Samples collected</td><td>834</td><td>761</td><td>343</td><td>23</td></tr>
<tr><td>Ayurvedic Samples tested</td><td>526</td><td>476</td><td>343</td><td>23</td></tr>
<tr><td>No of samples declared NSQ</td><td>17</td><td>08</td><td>30</td><td>08</td></tr>
<tr><td>No of consent for prosecution issued</td><td>14</td><td>05</td><td>28</td><td>08</td></tr>
</table>
</td></tr>
<tr><td>6.</td><td>West Bengal</td><td>
<table>
<tr><td>S.No</td><td>Year</td><td>Total number of cases of substandard, misbranded and adulterated AYUSH drugs</td></tr>
</table>
</td></tr>
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		1	2022	11
		2	2023	13
		3	2024	09
7.	Odisha	No cases of substandard, misbranded and adulterated AYUSH drugs reported from rural areas in the last three financial years in the State of Odisha.		
8.	Gujarat	Total Number of Not of Standard Cases in the last three financial years is 45 & the State Licensing authority has taken final departmental action under the provisions of the Drugs and Cosmetics act, 1940 & Rules their under.		
9.	Uttarakhand	In the last two years total 123 Sample found substandard quality. The action is taken by the Drug Inspector as per Drug and Cosmetic Act 1940 Rules thereunder. And also, necessary action taken against the manufacturers/Companies by State Licensing Authority.		
10	Haryana	Action has been taken as per Drugs and Cosmetics Act, 1940 and rules framed thereunder.		
11	UT of Ladakh	No cases reported in UT Ladakh.		
12	Madhya Pradesh	No such data collected.		
13	Manipur	No report as such.		
14	Puducherry	NIL		
15	Delhi	NIL		
16	Arunachal Pradesh	NIL		

Annexure-III

The details of awareness programs have been conducted to strengthen pharmacovigilance of Ayush drugs throughout the nation under the pharmacovigilance program for ASU & H drugs for practitioners, healthcare workers and other different cohort including general public to disseminate the awareness regarding patient safety are as follows: -

Year	Awareness Program	Beneficiaries
2018	1	50
2019	54	800
2020	60	4300
2021	118	14659
2022	292	23510
2023	586	43396
2024	1065	105148
2025 (Upto June 2025)	692	66255
Total	**2868**	**2,58,118**