

**GOVERNMENT OF INDIA
MINISTRY OF AYUSH**

**LOK SABHA
UNSTARRED QUESTION NO. 2217
TO BE ANSWERED ON 31.07.2026**

Assessment of Contamination in AYUSH Medicines

2217. Shri Shafi Parambil

Will the Minister of AYUSH be pleased to state:

- (a) whether the Government has conducted any nationwide assessment of heavy metal contamination, pharmaceutical adulteration and mislabelling in AYUSH medicines and if so, the findings thereof;
- (b) the number of samples collected and tested during the last five years, category-wise along with the number exceeding the prescribed limits for mercury, lead, arsenic and cadmium;
- (c) the details of the number of manufacturers found selling adulterated or mislabelled AYUSH medicines and the action taken against them;
- (d) whether the Government maintains data on adverse liver injury linked to AYUSH medicines and if so, the details thereof; and
- (e) whether the Government proposes to strengthen pharmacovigilance and introduce mandatory public disclosure of quality testing results for licensed AYUSH products and if so, the details thereof?

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

(a) As prescribed in Drugs and Cosmetics Act, 1940 and Drugs Rules, 1945, enforcement of the legal provisions relating to quality control, including testing, compliance and issuance of licenses of Ayush drugs, is vested with the Drug Controllers/ Licensing Authorities appointed by the concerned State/ Union Territory Governments. The notified officers under State/UT Governments are also empowered to enforce the provisions of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 & Rules made there-under. Quality surveillance of Ayush medicines is undertaken by the State/UT drug inspectors through periodic inspections, sampling and testing of drugs in Government-approved drug testing laboratories. Further, the Ministry of Ayush has established an Ayush Vertical in the Central Drugs Standard Control Organisation (CDSCO) to strengthen the enforcement of the provisions of the Drugs and Cosmetics Act, 1940 and the rules made thereunder. The Ayush Vertical undertakes regulatory activities, including conducting joint inspections of manufacturing units in coordination with the State Drug Inspectors and CDSCO officials to ensure pharmaceutical adulteration and mislabelling.

Ministry of Ayush undertakes surveillance of mislabeling in Ayush medicines in the form of misleading/ objectionable advertisements through the Pharmacovigilance Program for Ayush drugs under the Central Sector Scheme namely, Ayush Oushadhi Gunavatta Evam Utpadan Samvardhan Yojana (AOGUSY). The Program functions with an objective to monitor and report misleading advertisements relating to Ayush drugs for appropriate regulatory action along with reporting suspected Adverse Drug Reactions (ADRs).

In addition, Ministry of Ayush has launched Ayush Suraksha portal, wherein misleading advertisements, suspected adverse drug reactions and instances of mislabeling are reported and monitored for appropriate action.

(b) As per the information received from the State/UT Governments, the number of samples collected and tested during the last five years, category-wise along with the number exceeding the prescribed limits for mercury, lead, arsenic and cadmium are attached at Annexure-I

The Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a sub-ordinate organization under the Ministry of Ayush functions as the Appellate Drugs testing Laboratory for testing or analysis of Ayush drugs and receives samples from Government agencies under the provisions of Drugs & Cosmetics Act, 1940 & Rules made there-under for quality testing. During last five years, 372 samples of Ayush drugs have been tested by PCIM&H. The details are attached at Annexure II.

(c) As per the information received from the State/UT Governments, the details of the number of manufacturers found selling adulterated or mislabeled Ayush medicines and the action taken against them are attached at Annexure-III.

(d) Ministry of Ayush maintains data on suspected adverse drug reactions (ADRs) associated with Ayush drugs under the Pharmacovigilance Program. A reporting mechanism for adverse drug reactions is also available in the Ayush Suraksha portal. However, no specific case of suspected adverse liver injury linked to Ayush medicines has been reported under the Programme till date.

(e) Yes, Ministry of Ayush is implementing a Central Sector Scheme, namely Ayush Oushadhi Gunavatta evam Utpadan Samvardhan Yojana (AOGUSY) since 2021 for five years. The scheme has interalia one of the components, “Pharmacovigilance Program for Ayush Drugs” with its major objectives to keep vigilance over Ayush drugs and to reduce the pollution of misleading advertisements. The program is working through a three-tier network of a National Pharmacovigilance Centre (NPvCC), Five Intermediary Pharmacovigilance Centres (IPvCs) and 97 Peripheral Pharmacovigilance Centres (PPvCs) established across the country.

To strengthen the pharmacovigilance system for Ayush drugs, Ministry of Ayush has launched an IT enabled online portal “Ayush Suraksha” to track the reported Misleading Advertisements (MLAs)/Objectionable Advertisements (OAs) and suspected Adverse Drug Reactions (ADRs) on 30th May 2025. The portal features a centralized dashboard for

capturing of MLAs/OAs and tracking of suspected ADRs for prompt regulatory action and comprehensive data analysis.

Further Central Government has notified the Coordinator, National Pharmacovigilance Coordination Centre, All India Institute of Ayurveda, New Delhi, under Information Technology Act, 2000 as the nodal officer for the purpose of issuing notice to intermediaries in relation to any information, data or communication link residing in or connected to a computer resource controlled by the intermediary being used to commit the unlawful act, in respect to the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954, the National Commission for Indian System of Medicine Act, 2020 and the National Commission for Homeopathy Act, 2020 .CDSCO

Annexure-I

As per the information received from State/UT Licensing Authorities, number of samples collected and tested during the last five years, category wise along with the number exceeding prescribed limits for mercury, lead, arsenic and cadmium is as follows:

S. No.	State/UT	Year	Number of samples collected and tested during the last five years, category wise	Number exceeding prescribed limits for lead,Mercury,Arsenic,Cadmium
1.	Andaman & Nicobar	2022-23	00	NIL
		2023-24	05	
		2024-25	36	
		2025-26	13	
		2026-27 (till June 2026)	00	
2.	Tripura	2022-23	395	NIL
		2023-24	68	
		2024-25	145	
		2025-26	55	
		2026-27 (till 25-05-2026)	09	
3.	Odisha	2021-22	1901	NIL
		2022-23	1415	
		2023-24	650	
		2024-25	153	
		2025-26	892	
4.	Tamil Nadu	2022-23	2835	NIL
		2023-24	2320	NIL
		2024-25	1696	NIL
		2025-26	2692	NIL
		2026-27 (till June 2026)	813	NIL
5.	Telangana	Last five years	285	NIL
6.	Kerala	Number of samples collected and tested during the last five years-2675		1
		2021	378	
		2022	479	
		2023	540	
		2024	435	
		2025	843	

7.	Himachal Pradesh	2021-22	443	NIL
		2022-23	816	
		2023-24	576	
		2024-25	738	
		2025-26	353	
8.	Assam	2021	118	NIL
		2022	77	
		2023	364	
		2024	410	
		2025	366	
9.	Delhi	2021-22	433	NIL
		2022-23	335	
		2023-24	577	
		2024-25	694	
		2025-26	1312	
10.	Goa	2021-22	75	NIL
		2022-23	227	
		2023-24	114	
		2024-25	89	
		2025-26	191	
11.	Sikkim	2021-22	62	NIL
		2022-23	92	
		2023-24	101	
		2024-25	114	
		2025-26	115	
12.	Uttar Pradesh	NIL		
13.	Manipur	NIL		
14.	Madhya Pradesh	NIL		

Annexure-II

The details of the samples of ASU&H drugs has been tested by PCIM&H during last five years are attached as follows-

Year	Homoeopathy	ASU	Total
2022-23	239	28	267
2023-24	01	47	48
2024-25	01	19	20
2025-26	10	25	35
2026-27	01	01	02
Total	252	120	372

Annexure-III

State/UT wise details of the number of manufactures found selling adulterated or mislabeled Ayush medicines and the action taken against them are as follows:-

S.no.	Name of the State/ UT	Number of manufactures found selling adulterated or mislabeled Ayush medicines	Details of Action taken
1.	Tripura	Nil. No manufacturing unit is available in Tripura.	NA
2.	Kerala	Number of adulterated medicine from 2019 – 5 Legal action has been initiated against the manufacturers according to the provisions of Drugs and Cosmetics Act 1940	1. Final complaint against M/s Petlad Mahal Arogya Mandal Pharmacy, P.O, Piplata, Kheda, Gujarat filed before JFMC II, Kollam Case No.ST 2049/2024- Under Trial 2. Final complaint against M/s Agasthya Pharmaceuticals, Sidha Marma Chikitsalayam, S.S.I Unit, Thonnakkal (P.O), Mangalapuram, Thiruvananthapuram filed before JFMC II, Attingal Case No.ST 23/2021- Under Trial 3. Final complaint against M/s Petlad Mahal Arogya Mandal Pharmacy, P.O, Piplata, Kheda, Gujarat filed before JFMC II, KOLLAM Case No.CC 1862/2024- Under Trial 4. Final complaint against M/s Petlad Mahal Arogya Mandal Pharmacy, P.O, Piplata, Kheda, Gujarat filed before JFMC II, KOLLAM Case No.CC

			1863/2024- Under Trial 5. Final complaint against M/s Petlad Mahal Arogya Mandal Pharmacy, P.O, Piplata, Kheda, Gujarat filed before JFMC II, KOLLAM Case No.CC 1864/2024- Under Trial
		Number of mislabeled medicines from 2019 - 3	1. Final Complaint against M/s Bala Herbals, Industrial Estate, Edakkulangara, Karunagappally Filed before JFMC 1- Karunagappally Case No ST 585/2023- Under Trial 2. Final Complaint against M/s Altis Life Sciences, Khasra No-380,Suraj Majra Labana, Baddi- 173205, District Solan, H.P and Teleone Consumers Product pvt Ltd, P.O, Box No.10555, Pitam pura, New delhi- 110034 Filed before JFMC V,Vanchiyoor Case No CMP 530/2020- Under Trial 3. Final Complaint against AVN Formulations Pvt. Ltd 175-A,Vilachery Main Road, Madurai, Tamil nadu Filed before JFMC 3, Kozhikode Case No ST 147 12023- Under Trial
2.	Telangana	01	Show cause notice has been issues and the license of Karnataka Antibiotics & Pharmaceuticals Ltd., Plot No. 37, Site No.-34/4, nttf Main Road, Peenya

			Industrial Area, 2 nd Phase, Bangalore has been cancelled for other violations of schedule T of D & C Act
3.	Uttar Pradesh	NIL	
4.	Odisha	NIL	
5.	Manipur	NIL	
6.	Tamil Nadu	NIL	
7.	Delhi	NIL	
8.	Sikkim	NIL	
9.	Goa	NIL	
10.	Madhya Pradesh	NIL	
11.	Himachal Pradesh	NIL	