GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO. 3532
TO BE ANSWERED ON 24TH MARCH, 2026

Monitoring of high metal content in ayush drugs

3532 **Dr. Fauzia Khan:**

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

(a) whether Government has implemented the recommendations of Department-related Standing Committee (DRSC)'s Report 2024 on monitoring heavy metal content in AYUSH drugs;

(b) if so, the details thereof and if not, the reasons therefor;

(c) the steps taken to strengthen pharma-covigilance and post-marketing surveillance of AYUSH medicines;

(d) the status of strengthening existing NABL-accredited laboratories and timeline for additional testing facilities;

(e) the details of action against manufacturers exceeding FAO/WHO limits, including licences suspended, penalties imposed and product recalls activated; and

(f) the real-time monitoring systems implemented and consumer compensation framework for health damages from heavy metal toxicity?

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

(a) to (c) The 156th report of Department-Related Parliamentary Standing Committee on Health and Family Welfare has raised its concern over the high metal contents in the Ayush drugs. Further, the Committee recommended Ministry of Ayush to strengthen regulatory framework to conduct regular post-marketing surveillance. The Ministry has taken following initiatives in this regard:

i. Ministry of Ayush is implementing a Pharmacovigilance Program for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs under its Central Sector Scheme-Ayush Oushadhi Gunvatta evam Uttpadan Samvardhan Yojana (AOGUSY) which routinely report suspected Adverse Drug Reactions (ADRs) to the respective State/UT Licensing Authorities for necessary action.

ii. Further, to strengthen the pharmacovigilance program for Ayush drugs, Ministry of Ayush has launched an IT enabled online portal “Ayush Suraksha” on 30th May, 2025 to report ADRs related to the Ayush medicine.

The portal features a centralized dashboard for real-time tracking of suspected ADRs for prompt regulatory action and comprehensive data analysis. The portal is aligned with the National Pharmacovigilance Program and integrates data from three-tier Pharmacovigilance Centres and forwards complaints to the concerned authorities, including State/UT Licensing Authorities (Ayush) and Central Govt. bodies such as Ministry of Information and Broadcasting (MoIB), Central Consumer Protection Authority (CCPA), National Commission for Indian System of Medicine (NCISM), National Commission for Homoeopathy (NCH), Press Council of India (PCI), Food Safety and Standards Authority of India (FSSAI) for its resolution.

iii. As prescribed in Drugs and Cosmetics Act, 1940 and Drugs Rules, 1945, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Sowa-Rigpa, 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 Drugs Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia. Drug Inspectors regularly collect medicine samples regularly from manufacturing firms and sale counters, send them to State Drug Testing Laboratory for quality testing and take appropriate action(s) on the basis of tests reports as per the provisions of Drugs and Cosmetics Act,1940 and Drugs Rules, 1945.

iv. Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a 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 and compliance to this quality standards are mandatory for the manufacturing for sale of ASU&H drugs across the country. So far, 2325 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. In addition to above, supporting documents in the form of Macro, Microscopic & TLC Atlas on 392 single drugs incorporated in Ayurvedic Pharmacopoeia of India (API) has also been published. Further, 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.

(d) Ministry of Ayush is implementing Central Sector Scheme Ayush Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) which includes, inter-alia, a component to strengthen and up-grade Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards like WHO-GMP and NABL accreditation respectively, thereby ensuring safe, effective, and quality Ayush medicines and enhancing their credibility in domestic as well as international markets.

Further, Rule 160 A to J of the Drugs Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratory for carrying out tests of identity, purity, quality and strength of Ayurveda, Siddha, Sowa-Rigpa and Unani (ASSU) drugs. As on date, 108 laboratories are approved or licensed under the provisions of Drugs Rules, 1945 for manufacturers. Further, there are 34 Drug Testing Laboratories of State/UTs for testing quality of ASSU drugs and raw materials including legal samples.

(e) As prescribed in the Drugs and Cosmetics Act, 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Sowa-rigpa, Unani and Homoeopathy drugs, is vested with the State Drugs Controllers/ State Licensing Authorities appointed by the concerned State/ UT Government.

No State/UT Licensing Authorities reported the instances of exceeding Food and Agriculture Organization (FAO)/ World Health Organization (WHO) limits.

(f) Ministry of Ayush is implementing a Pharmacovigilance Program for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs under its Central Sector Scheme-Ayush Oushadhi Gunvatta evam Uttpadan Samvardhan Yojana (AOGUSY). The program operates through a dedicated three-tier network comprising one National Pharmacovigilance Co-ordination Centre (NPvCC), five Intermediary Pharmacovigilance Centres (IPvC) and ninety seven Peripheral Pharmacovigilance Centres (PPvC) across the country. The All India Institute of Ayurveda (AIIA), New Delhi under Ministry of Ayush serves as the NPvCC for the implementation of the

program. All PPvCs/IPvCs routinely report suspected Adverse Drug Reactions (ADRs) to the respective State/ UT Licensing Authorities for necessary action.

Further, as per clause 1.1 (N) of Schedule T of Drugs Rules, 1945, all the finished goods of Ayurveda, Siddha, Sowa-Rigpa and Unani (ASSU) are tested as per their respective pharmacopoeial standards and where the tests are not available, the test should be performed according to the manufacturer's specification or other information available. Routine inspections are done by the Drug Inspectors of concerned State/UTs and samples of Ayush medicines are lifted and sent to State/UT Government laboratories for test/analysis for heavy metal limit wherever applicable.

Section 33EEB of the Drugs and Cosmetics Act, 1940 prohibits manufacturing for sale or for distribution of ASSU drugs except in accordance with respective standards and section 33EEC of the Drugs and Cosmetics Act, 1940 prohibits manufacturing for sale or for distribution of misbranded, adulterated and spurious ASSU drugs. Further, penalties are mentioned under section 33I of the Drugs and Cosmetics Act, 1940 for manufacturing for sale of medicines mentioned under section 33EEB and section 33EEC of the Drugs and Cosmetics Act, 1940.

Schedule E(I) of the Drugs Rules, 1945 comprises a list of poisonous substances, including heavy metals like arsenic, mercury, which are processed through defined methodologies as mentioned in authoritative texts of First Schedule of Drugs and Cosmetics Act, 1940 specifically Shodhana (Purification) and Marana (Incineration) to ensure safety and therapeutic efficacy for human consumption. Further, as per Rule 161 of the Drugs Rules, 1945, it is mandatory for manufacturers to clearly mention on the label and container of Ayush medicines containing ingredients listed under Schedule E(I) that "Caution: To be taken under medical supervision", in both English and Hindi.

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