GOVERNMENT OF INDIA
MINISTRY OF AYUSH

LOK SABHA
UNSTARRED QUESTION NO. 876
TO BE ANSWERED ON 7th February 2025

"Surveillance of AYUSH Medicine"

876. Shri Sachithanantham R:

Will the Minister of Ayush be pleased to state:

(a) whether the Government has taken any initiatives to conduct post-marketing surveillance of AYUSH medicines to track their safety and efficacy, harmonise standards of AYUSH medicines with international norms and develop systems to report adverse events related to medicines in the country in view of the recommendation of the Standing Committee on Health and Family Welfare related to high metal content;

(b) if so, the details thereof; and

(c) if not, the reasons therefor?

ANSWER

THE MINISTER OF STATE (IC) OF THE 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;

1. Ministry of Ayush has implemented a Central Sector Scheme- Ayush Oushadhi Gunavatta evam Uttpadan Samvardhan Yojana (AOGUSY). One of the components of this scheme is Pharmacovigilance Program for Ayurveda, Siddha, Unani, and Homoeopathy (ASU & H) Drugs including surveillance of misleading advertisements. A three tier structure is established across the country since 2018 comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Five Intermediary Pharmacovigilance Centres (IPvCs) and Ninety-nine Peripheral

Pharmacovigilance Centres (PPvCs). 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. The vision of the program is to improve patient safety in Indian population by monitoring the drug safety in ASU & H drugs by keeping vigilance over the post marketing use of ASU&H drugs and reporting culture of suspected Adverse Drug Reactions, keeping surveillance of misleading advertisements appearing in print and electronic media, organising awareness events regularly across the country to generate awareness regarding the Ayush therapeutic approaches and educating healthcare professionals about the systematic use of Ayush drugs.

2. 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 and Cosmetics 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 and Cosmetics 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 and Cosmetics 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 .

3. 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. The details of work done by PCIM&H are attached at Annexure.

Annexure

Details of work done by PCIM&H

1. 2259 quality standards on raw materials (Single Drugs of plant/animal/Mineral/metal/ Chemical origin) used in ASU&H have been published, the details are as below;

Name of Pharmacopoeia	**Published quality standards of single drugs**
Ayurvedic Pharmacopoeia on India (Part I, Vol. I to X)	665
Siddha Pharmacopoeia on India (Part I Vol. I to II)	139
Unani Pharmacopoeia on India (Part I Vol. I to VII)	338
Homoeopathic Pharmacopoeia on India (Vol. I to X)	1117

2. 405 quality standards of ASU formulations have also been published in respective Pharmacopoeias. The details as follows:

Name of Pharmacopoeia	**Published quality standards of formulations**
Ayurvedic Pharmacopoeia on India (Part II, Vol. I to IV)	202 and 01 standalone quality standard
Siddha Pharmacopoeia on India (Part II)	01 standalone quality standard
Unani Pharmacopoeia on India (Part II Vol. I to IV)	200 and 01 standalone quality standard

3. **2799** formulary specifications of ASU drugs are also published in Formularies of respective system. The details as follows:

Formulary	**Specifications**
Ayurvedic Formulary of India	1035 (Part I to IV) and 01 standalone formulary specification
Siddha Formulary of India	533 (Part I to III) and 01 standalone formulary specification
National Formulary of Unani Medicine	1229 (Part I to VI) and 01 standalone formulary specification

4. In addition to above, supporting documents in the form of Macro-Microscopic & TLC Atlas on 351 single drugs incorporated in API are also published.

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