GOVERNMENT OF INDIA
MINISTRY OF AYUSH

LOK SABHA
UNSTARRED QUESTION NO.4735
TO BE ANSWERED ON 28th March 2025

"AYUSH Medicines"

4735. Adv. Chandra Shekhar:

Will the Minister of Ayush be pleased to state:

(a) whether the Government is aware of the high metal content in AYUSH medicines that have been highlighted, posing serious health risks to consumers and if so, the details thereof;

(b) the current actions the Government have undertaken to the enhance quality control measures and ensure compliance with safety standards; and

(c) the manner in which the Government plan to implement post-marketing surveillance and harmonize AYUSH medicine standards with international norms to protect public health effectively?

ANSWER

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

(SHRI PRATAPRAOJADHAV)

(a) and (b) As per the information received from various States/UTs, no instances of high metal content in Ayush medicines have been reported. Further the Ministry of Ayush has taken following initiatives to enhance the quality control measures and ensure compliance with safety standards;

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 for Ayurveda, Siddha, Unani drugs and Homoeopathy drugs respectively of the Drugs Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

2. Drug Inspectors collect medicine samples regularly from manufacturing firms or sale shops with in their jurisdiction and sent it to Drug Testing Laboratory under Drug Control department for quality testing and if any sample found to be Not of Standard Quality, appropriate action initiates 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.

(c) Pharmacovigilance Centres for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs set up in different parts of the country under the Central Sector Scheme -Ayush Oushadhi Gunavatta evam Uttpadan Samvardhan Yojana(AOGUSY) are mandated to report adverse drug reaction through a three-tier network of a National Pharmacovigilance Centre (NPvCC), Five Intermediary Pharmacovigilance Centres (IPvCs) and 99 Peripheral Pharmacovigilance Centres (PPvCs).

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.

The Central Drugs Standard Control Organization (CDSCO) provides Certification of Pharmaceutical Product (COPP) as per World Health Organization (WHO) guidelines, which is extended to Ayurveda, Siddha and Unani (ASU) medicines.

The Central Sector Scheme- Ayush Oushadhi Gunavatta evam Uttpadan Samvardhan Yojana(AOGUSY), under the component of Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards supports Ayurveda, Siddha, Unani and Homoeopathy(ASU&H) Pharmacies for upgrading to World Health Organisation(WHO)- Good Manufacturing Practices(GMP) standards.

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