

**GOVERNMENT OF INDIA  
MINISTRY OF AYUSH**

**LOK SABHA  
UNSTARRED QUESTION NO. 3892  
TO BE ANSWERED ON 11<sup>th</sup> AUGUST, 2023**

**“QUALITY OF AYURVEDIC MEDICINES”**

**3892. SHRIMATI SHARDABEN ANILBHAI PATEL:  
SHRI MITESH RAMESHBHAI PATEL (BAKABHAI):**

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

- (a) whether any Ayurvedic medicines in circulation has not been complying with the provisions of the Drugs and Cosmetics Act, 1940; and
- (b) if so, the details thereof along with the number of cases of severe side effects and fatalities noticed due to the consumption of such uncertified medicines?

**ANSWER  
THE MINISTER OF AYUSH  
(SHRI SARBANANDA SONOWAL)**

(a) and (b) As prescribed in 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 and Unani 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. 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 of Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

Pharmacovigilance Centres for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs set up in different parts of the country under the Central Scheme of Ministry of Ayush are

mandated to monitor and report the misleading advertisements to the respective State Regulatory Authorities. A three tier structure comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs) is established. 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. Objectionable advertisements are being reported to the respective State Licensing Authorities by PPvC at regular intervals.

As per the information received from the government of State/UTs, 03 cases of adulteration in Ayush products have been reported by State government of Gujarat, 113 cases of Not of Standard Quality (NSQ) in Ayush products have been reported by State government of Kerala and 99 cases of Not of Standard Quality (NSQ) in Ayush products have been reported by State government of Maharashtra. No cases of severe side effects and fatalities due to the consumption of such medicines have been reported.

\*\*\*\*\*