

**GOVERNMENT OF INDIA
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY, UNANI,
SIDDHA AND HOMOEOPATHY (AYUSH)**

**LOK SABHA
STARRED QUESTION NO. 159
TO BE ANSWERED ON THE 16TH DECEMBER, 2022**

PROMOTION OF AYUSH PRODUCTS

***159. MS. RAMYA HARIDAS:**

Will the Minister of AYUSH be pleased to state:

- (a) whether the Ministry proposes to promote better quality AYUSH products on a larger scale for maximum benefit of the consumers;
- (b) if so, the challenges being faced by the Ministry in promoting such products for their wider use by the consumers;
- (c) whether any cases of malpractice in manufacturing of different AYUSH medicines have been detected; and
- (d) if so, the preventive measures taken in this regard?

**ANSWER
THE MINISTER OF AYURVEDA, YOGA & NATUROPATHY, UNANI,
SIDDHA AND HOMOEOPATHY (AYUSH)**

(SHRI SARBANANDA SONOWAL)

(a) to (d) A Statement is laid on the Table of the House.

**STATEMENT REFERRED TO IN REPLY TO LOK SABHA
STARRED QUESTION NO. 159* FOR 16TH DECEMBER, 2022**

(a) to (d) Yes Madam, Ministry of Ayush has taken following steps to promote better quality AYUSH products in the country:

i. Schemes to support Ayurvedic medicines production: Under National Ayush Mission (NAM) from 2014-2021, apart from other services Grant-in-aid were also provided for Strengthening of State Government ASU&H Pharmacies. At present, Central Sector Scheme for Ayush Oushadhi Gunavatta evam Uttpadan Samvardhan Yojana (AOGUSY) has been implemented for the year 2021-2026. The components of the AYUSH Oushadhi Gunvatta Evam Uttpadan Samvardhan Yojana (AOGUSY) Scheme are as under;

A. Strengthening and up-gradation of Ayush Pharmacies and Drug Testing Laboratories to achieve higher standards.

B. Pharmacovigilance of ASU&H drugs including surveillance of misleading advertisements.

C. Strengthening of Central and State regulatory frameworks including Technical Human Resource & Capacity Building programs for Ayush drugs.

D. Support for development of standards and accreditation/ certification of Ayush products & materials in collaboration with Bureau of Indian Standards (BIS), Quality Control of India (QCI) and other relevant scientific institutions and industrial R&D centres.

ii. Ministry of Ayush has setup Pharmacopoeia Commission for Indian Medicines and Homoeopathy (PCIM&H), as a subordinate office under Ministry of Ayush to lay down Pharmacopoeial Standards and Formulary specifications for Ayurveda, Siddha, Unani & Homoeopathy (ASU&H) drugs, which serve as official compendia for ascertaining the identity, purity and strength of the drugs included therein.

iii. In addition to the above, for facilitating exports, Ministry of Ayush encourages following certifications of AYUSH products as per details below:-

- Certification of Pharmaceutical Products (CoPP) as per WHO Guidelines for herbal products.
- Quality Certifications Scheme implemented by the Quality Council of India (QCI) for grant of AYUSH Premium mark to Ayurvedic, Siddha and Unani products on the basis of third party evaluation of quality in accordance with the status of compliance to international standards.

iv. 27 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. As on date 81 laboratories are approved or licensed under Rule -160 A to J of the provisions of Drugs and Cosmetics Rules, 1945 for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials.

v. 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.

v. Ministry of Ayush has organized a three day Global Ayush Investment and Innovation Summit (GAIIS) from 20 -22 April, 2022 at Mahatma Mandir, Gandhinagar, Gujarat. The Global Ayush investment and Innovation Summit, 2022 was a distinctive effort by the Government of India to attract the world's attention to India's ancient wisdom and traditional knowledge, and capitalize on it to pave the way for a sustainable future. The Summit was organized in line with Sustainable Development Goal Number 3 of promoting "Good Health and Well-being." A total of five plenary sessions, eight roundtables, six workshops, and two symposiums were organized and 90 eminent speakers and 100 exhibitors participated during GAIIS.

vii. Ministry of Ayush has implemented Central Sector Scheme for Promotion of Information, Education and Communication (IEC) in AYUSH to take up initiatives for propagation and promotion of Ayush systems of medicines. The objectives of this scheme are as follows –

- Pursue activities in the areas of Information, Education and Communication to fulfill the mandate of "propagation" of AYUSH" Systems of Healthcare, assigned to the Ministry in the Government of India (Allocation of Business) Rules 1961. Creation of awareness amongst the citizens about the efficacy of the Ayush systems, their cost effectiveness and the availability of ASU&H drugs services and other solutions. Utilizing various communication channels for this purpose, and produce IEC material including digital and audio-video publicity material to achieve the objective of health for all;

- Dissemination of information on proven results of Research and Development work conducted in Ayush Systems at National/ State level through Fairs, Exhibitions, Seminars, Workshops, Symposiums and educational platforms. Planning and organizing the observation of important Days;
- Providing information and communication forums where horizontal and vertical interaction among stakeholders of Ayush Systems can take place through digital events, conferences, seminars and fairs/ melas at State and National levels and encourage stakeholders to participate in them.
- Organising events for the propagation and promotion of Ayush Systems, like Seminars, Conferences, Symposiums and Workshops (including in digital mode) on AYUSH Systems and providing information to shareholders relating to recent development in AYUSH sector.

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, Unani and Homoeopathic 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 Homoeopathic 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.

As per the information received from various States/ UTs, cases of malpractice detected in manufacturing of different AYUSH medicines are as follows -

S.no.	Name of the State/UTs	No. cases of malpractice detected in manufacturing of different AYUSH medicines and preventive measures taken
1.	Andhra Pradesh	04 license cancelled & Unit seized , 03 license suspended and 01 case filed in Court of law and convicted
2.	Assam	52 drug samples were found were non-compliant to Drugs and Cosmetics Act, 1940 from 2020 to 2021
3.	Chhattisgarh	NIL
4.	Gujarat	02 product permission has been cancelled, 01 court case launched and 03 Ayush products are under investigation during 2019 to 2022.

5.	Karnataka	NIL
6.	Kerala	113 samples of Ayurvedic medicines were found as Not of Standard Quality (NSQ)
7.	Manipur	NIL
8.	Mizoram	04 drugs (02 Ayurvedic) drugs were found to be non-compliant to Drugs and Cosmetics Act, 1940.
9.	Maharashtra	21 samples of Ayurvedic medicines were found as Not of Standard Quality (NSQ) during 01.04.2021 to 31.10.2022.
10.	Nagaland	NIL
11.	Odisha	NIL
12.	Punjab	NIL
13.	Rajasthan	License of 02 firms suspended for one year, 02 license of the sub-standard drug was cancelled and license of 09 sub-standard medicines was suspended for 06 months.
14.	Sikkim	NIL
15.	Tamil Nadu	01 Ayush product has been suspended for one month
16.	Uttar Pradesh	NIL
17.	Madhya Pradesh	NIL
18.	Uttarakhand	NIL
19.	Delhi	01 manufacturing license has been suspended and orders has been issued to 02 manufacturers to stop manufacture and distribution
20.	Lakshadweep	NIL
21.	Puducherry	NIL
22.	Chandigarh	NIL
